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Effect of adjuvant frequency-specific microcurrents on pain and disability in patients treated with physical rehabilitation for neck and low back pain☆

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ABSTRACT

Objectives: To evaluate the efficacy of adjuvant frequency-specific microcurrent (FSM) application on pain and disability in patients treated with physical rehabilitation for mechanical low back pain (LBP) and neck pain (NP).
Methods: In this retrospective case-control study, pre- and post-treatment numerical pain rating scale (NPRS) score, Oswestry disability index (ODI) score, neck disability index (NDI) score, disability categories, and treatment outcome categories were compared between 213 patients in the FSM group (167 patients with LBP, 46 patients with NP) and 78 patients in the control group (61 patients with LBP, 17 patients with NP).
Results: In LBP patients, mean post-treatment NPRS score was significantly lower ($p = 0.02$) and a significantly higher percentage of patients were in the ≤ 3 NPRS score ($p = 0.02$), in the minimal disability ($p = 0.01$), and the full success ($p = 0.006$) categories post-treatment in the FSM group when compared to the control group. In NP patients, there was no significant difference in the post-treatment pain intensity, disability or treatment outcome when the 2 groups were compared.
Conclusions: The use of adjuvant FSM application in patients treated with physical rehabilitation for LBP significantly improved pain and disability when compared to patients in the control group. Frequency specific microcurrent could be a useful adjuvant in the rehabilitation treatment of patients with low back pain.

1. Introduction

Electrophysical modalities such as transcutaneous electrical nerve stimulation (TENS), interferential current stimulation, diadynamic current stimulation, and high-voltage electrical stimulation are used for pain management in patients with musculoskeletal conditions (Almeida et al., 2018; Rajfur et al., 2017; Gibson et al., 2019; Logan et al., 2017; White et al., 2017). However, the evidence is lacking in the literature about the efficacy of such modalities on acute or chronic low back pain (LBP) or neck pain (NP). A recent systematic review and meta-analysis reported inconclusive evidence of benefits of TENS in patients with low back pain patients due to the low quality of studies available in the literature (Resende et al., 2018). However, another systematic review which analyzed 700 patients, reported that although TENS does not improve symptoms of lower back pain, it may offer short-term improvement of functional disability (Wu et al., 2018).

Frequency-specific microcurrent (FSM) is an electrophysical modality used in pain management that delivers very low-intensity electric current to tissues within the microampere (μA) range, approximately 1000 times lower than the current intensity used in TENS (McMakin, 2011, 2017). Microcurrent application is based on the principle that a current closer to the cellular current of the body can overcome electrical resistance of injured or inflamed tissue, restore cellular homeostasis, and facilitate tissue regeneration in contrast to TENS which primarily works by blocking the transmission of pain signals (McMakin, 2011, 2017). Although the mechanism of action of FSM is not yet clear, these microcurrents of

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physiological amperage when delivered to damaged or inflamed tissues is said to alter cell membrane function, reduce inflammation, and promote healing by maintaining intracellular Ca^{2+} homeostasis and upregulating ATP production (McMakin, 2011; Kwon et al., 2014; Fujiya et al., 2015; Lambert et al., 2002).

Although previous studies have reported the efficacy of microcurrent in improving muscle function in musculoskeletal conditions such as delayed onset muscle soreness, congenital muscular torticollis, spastic myocontracture in cerebral palsy, and age-related muscle weakness (Lambert et al., 2002; Curtis et al., 2010; Kim et al., 2009; Mäenpää et al., 2004; Kwon et al., 2017), literature is lacking on the effect of FSM application on pain and disability in patients with LBP or NP. Hence, this study aimed to determine the efficacy of adjuvant FSM application on pain and disability in patients treated with physical rehabilitation for LBP and NP. We hypothesized that the use of adjuvant FSM application in patients treated with physical rehabilitation for LBP and NP will significantly improve pain and disability when compared to patients where FSM is not used.

2. Patients and methods

2.1. Study design

In this retrospective analysis, electronic records of routinely collected data from all patients treated for low back pain (LBP) and neck pain (NP) at 3 outpatient clinics specializing in spine rehabilitation (QI Spine Clinic, Pune) from October 2016 to January 2019 were analyzed. The inclusion criterion was all patients with LBP or NP, more than 20 years of age, who underwent physical rehabilitation treatment at our clinics. The exclusion criteria were patients with inflammatory conditions such as rheumatoid arthritis and spondyloarthropathies, patients where peripheral joints such as hip, knee and ankle joints were involved, patients with structural kyphotic or scoliotic deformities, patients with peripheral neuropathy, patients with complex regional pain syndrome (CRPS), patients with lumbar canal stenosis (LCS) and, patients who did physiotherapy for less than 1 month or more than 3 months at the centre.

2.2. Study population

Based on the inclusion criteria, 1187 patients who underwent treatment for LBP and NP at the outpatient clinics were eligible to be part of this study. Among the eligible patients, 811 patients received adjuvant FSM therapy (FSM group) whereas 376 patients did not receive the adjuvant FSM therapy (control group) during their treatment for LBP or NP. Based on the exclusion criteria, 93 patients were excluded due to inflammatory causes of LBP or NP, peripheral neuropathy or joint involvement, associated kyphotic or scoliotic deformities, CPS and LCS and 505 patients were excluded based on the duration of treatment of less than 1 month or more than 3 months in the FSM group. Similarly, based on the exclusion criteria, 48 patients were excluded due to inflammatory causes of LBP or NP, peripheral neuropathy or joint involvement, associated kyphotic or scoliotic deformities, CPS and LCS and 250 patients were excluded based on the duration of treatment of less than 1 month or more than 3 months in the control group. Hence, data from 213 patients in the FSM group and data from 78 patients in the control group were analyzed and compared for this study. This study was approved by an Institutional Ethics Committee and was performed as per the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

2.3. Outcome measures

All patients were evaluated clinically before and during treatment for their LBP or NP. A thorough history of presenting complaints, past illness, previous surgical or non-surgical treatment or any red flag conditions (recent trauma, night or at rest pain, fever, unexplained weight loss, progressive motor or sensory deficit, bowel or bladder symptoms, history of cancer, chronic steroid use, and immunosuppression) was recorded. All patients were clinically examined for posture, lumbar spine movement, motor and sensory function (myotomal and dermatomal loss) by a physiotherapist in the clinic. The intensity of LBP or NP was recorded using the numerical pain rating scale (NPRS) with pain intensity ranging from "0" (no pain) to "10" (worst pain imaginable) and functional disability was recorded using the Oswestry disability index (ODI) or Neck disability index (NDI) before and after treatment (Childs et al., 2005; Fairbank and Pynsent, 2000; Vernon, 2008). Using the Mechanical Diagnosis and Therapy (MDT) system, all patients were evaluated by movement testing and diagnosed as reducible derangement, irreducible degrangement, postural syndrome, dysfunction syndrome, or others by a senior physiotherapist in the clinic (McKenzie and May, 2003, 2008).

2.4. Treatment protocol

A multimodal, active rehabilitation protocol involving a combination of patient education, pain management using directional movements with or without application of frequency-specific microcurrents (FSM), and strength and stabilization exercises was administered to all patients in an outpatient clinic. Rehabilitation protocol was varied and personalized based on the severity of pain on NPRS and response to movement testing. All patients, during the first consultation, were educated about and recommended application of FSM as an adjuvant to physical therapy to improve pain and function, especially when the NPRS score was >3 by the consulting physiotherapist. However, the decision to use FSM application was left to the patient. Based on the severity of LBP or NP on NPRS during the first assessment, patients were advised light extension/flexion mobilization exercises for muscle activation, maintaining proper posture and rest (breaking posture and going to a non-loading position like lying supine) when required during activities of daily living for a maximum of 1 week if NPRS score was $\geq$7. Patients who opted for FSM therapy were administered FSM as a 30-min session, every day during the first 1 week of treatment. Once the pain on NPRS score was 4–7 or in patients presenting with pain on NPRS score 4–7, movement testing was done using the MDT method to determine directional preference. Patients were then advised directional movements that were performed under supervision by the treating physiotherapist and advised to be continued at home at frequent intervals. Patients were reviewed every week for progress or improvement in pain and function. Once the pain on NPRS was <4, paraspinal muscle strengthening and stabilization exercises were administered.

All patients underwent a minimum rehabilitation treatment of 30 days and a maximum of 90 days. A minimum of 6 supervised physiotherapy sessions at the clinic was advised to all patients. Post-treatment clinical assessment was performed at the time of discharge to determine NPRS score, ODI/NDI score and disability category. Treatment outcome was considered a full success if the patient shifted to a disability category of "minimal" and had pain improvement on NPRS of >80%, a partial success if the patient improved in disability by one category (e.g.: a shift from severe to moderate category) and pain improvement on NPRS of 30%–80% , and a failure if patients did not fall into the full or partial success category at the end of treatment.

2.5. Statistical analysis

Pre-treatment baseline parameters such as gender ratio, age, lifestyle, history of night pain, response of pain to movement testing, anatomical case type, treatment sessions done and total treatment period were analyzed. Similarly, clinical outcome data such as NPRS score, percentage of NPRS score improvement, ODI/NDI score, disability category, and treatment outcome category were analyzed. Clinical outcome parameters such as NPRS score, ODI/NDI score, change in disability category and treatment outcome category were compared before and after treatment between the FSM and control groups to determine the effectiveness of adjuvant FSM therapy. The Fisher's test or Chi-square with Yates' was used to compare categorical data whereas the *t*-Test was used to compare continuous data within and between the 2 groups. Statistical significance was accepted for p values less than 0.05 in all tests. Statistical analysis was performed using the SPSS (ver. 20.0) statistical analysis software (SPSS Science Inc, Chicago, IL).

3. Results

3.1. Comparison of baseline parameters between FSM vs control groups

The baseline characteristics of the 213 patients in the FSM group and 78 patients in the control group are compared in Table 1. The mean age ($p = 0.15$), mean BMI ($p = 0.83$), gender ratio ($p = 0.88$), anatomical case type ($p = 1.00$), lifestyle ($p = 0.43$), presence of night pain ($p = 0.88$), diagnosis based on MDT ($p = 1.00$), response to movement testing ($p = 1.00$), mean treatment duration ($p = 0.85$) and the mean number of treatment sessions done by the patients ($p = 1.00$) were not significantly different when the 2 groups were compared (Table 1).

3.2. Comparison of clinical outcomes between FSM vs control groups

Clinical outcomes in patients in the FSM group and patients in the control group are compared in Table 2. Pre-treatment, the mean NPRS score ($p = 0.44$), mean ODI/NDI score ($p = 0.16$), distribution of patients in NPRS categories ($p = 0.37$), and distribution of patients in disability categories ($p = 0.66$) were not significantly different when the 2 groups were compared (Table 2). Post-treatment, the mean NPRS score was significantly lower ($p = 0.01$) in the FSM group compared to the control group whereas the distribution of patients in NPRS categories was not significantly different ($p = 0.10$) when the 2 groups were compared. The post-treatment mean ODI/NDI score was not significantly different ($p = 0.10$) when the two groups were compared whereas a significantly higher percentage of patients ($p = 0.03$) were in the minimal disability category in the FSM group when compared to patients in the control group (Table 2). Overall, in terms of treatment outcome, a significantly higher percentage of patients were in the full success ($p = 0.03$) and the partial success ($p = 0.04$) categories in the FSM group when compared to the control group.

3.3. Comparison of clinical outcomes between FSM vs control groups in patients with low back pain (LBP)

A total of 167 patients (78.5%) in the FSM group had LBP whereas 61 patients (78%) in the control group had LBP. Pre-treatment, the mean NPRS score ($p = 0.49$), mean ODI score ($p = 0.25$), distribution of patients in NPRS categories ($p = 0.37$), and distribution of patients in disability categories ($p = 0.66$) were not significantly different when the 2 groups were compared (Table 3). Post-treatment, the mean NPRS score was significantly lower ($p = 0.02$) in the FSM group compared to the control group and a significantly higher percentage of patients ($p = 0.02$) were in the $\leq$3 NPRS score category in the FSM group when compared to the control group (Fig. 1). Similarly, a significantly higher percentage of patients ($p = 0.01$) were in the minimal disability category in the FSM group when compared to the control group (Fig. 2). However, the post-treatment mean ODI score was not significantly different ($p = 0.09$) when the two groups were compared (Table 3). Overall, in terms of treatment outcome, a significantly higher percentage of patients were in the full success ($p = 0.006$) category in the FSM group when compared to the control group (Fig. 3).

3.4. Comparison of clinical outcomes between FSM vs control groups in patients with neck pain (NP)

A total of 46 patients (21.5%) in the FSM group had NP whereas 17 patients (22%) in the control group had NP. Pre-treatment, the mean NPRS score ($p = 0.35$), mean NDI score ($p = 0.50$),

Table 1
Comparison of demographic parameters between the frequency-specific microcurrent (FSM) and control groups.

Parameters	FSM group	Control (Non-FSM) group
Number of patients (n)	213	78
Mean Age (yrs)	48.5 ± 14.8 (46.5–50.4)	45.7 ± 14.8 (42.3–49)
Mean BMI (kg/m^2)	25.8 ± 3.8 (25.2–26.3)	25.9 ± 3.4 (25.1–26.6)
Gender		
Males	142 (66.5%)	50 (64%)
Females	71 (33.5%)	28 (36%)
Case Type		
Lower back	167 (78.5%)	61 (78%)
Neck	46 (21.5%)	17 (22%)
Primary diagnosis		
Irreducible derangement	4 (2%)	1 (1.5%)
Reducible derangement	209 (98%)	77 (97%)
Lifestyle		
Sedentary	161 (75%)	54 (69%)
Semi-active	26 (12.5%)	11 (14%)
Active	26 (12.5%)	13 (17%)
Night pain	101 (47.5%)	35 (45%)
Mean sessions done	16 ± 6.2 (15.1–16.8)	16 ± 6.5 (14.5–17.4)
Mean treatment period (days)	56.6 ± 16.8 (54.3–58.8)	57 ± 16.8 (53.2–60.7)

All values presented as mean ± SD (95% confidence interval) or number (percentage).
BMI- body mass index.

Table 2
Comparison of clinical outcomes between the frequency-specific microcurrent (FSM) and control groups.

Parameters	FSM group	Control (Non-FSM) group
Number of patients (n)	213	78
Mean pre-treatment NPRS	5.9 ± 1.9 (5.6–6.1)	5.7 ± 2.2 (5.2–6.1)
Mean post-treatment NPRS	1.1 ± 1.7 (0.8–1.3)	1.7 ± 2.2 (1.2–2.1)
Mean pre-treatment ODI/NDI score	44.5 ± 17.5 (42.1–46.8)	41.3 ± 17.3 (37.3–45.2)
Mean post-treatment ODI/NDI score	16.9 ± 15 (14.8–18.9)	20.1 ± 15.1 (16.6–23.5)
Pre-treatment NPRS score		
≤3	19 (9%)	8 (10.5%)
4–7	145 (68%)	48 (61.5%)
>7	49 (23%)	22 (28%)
Post-treatment NPRS score		
≤3	192 (90%)	63 (81%)
4–7	19 (9%)	12 (15%)
>7	2 (1%)	3 (4%)
Pre-treatment disability category		
Bed-ridden	4 (2%)	2 (2.5%)
Crippled	34 (16%)	6 (7.5%)
Severe	78 (36.5%)	31 (40%)
Moderate	79 (37%)	30 (38.5%)
Minimal	18 (8.5%)	9 (11.5%)
Post-treatment disability category		
Bed-ridden	0 (0%)	0 (0%)
Crippled	5 (2.5%)	1 (1.5%)
Severe	14 (6.5%)	9 (11.5%)
Moderate	32 (15%)	20 (25.5%)
Minimal	162 (76%)	48 (61.5%)
Treatment outcome category		
Full success	159 (74.5%)	46 (59%)
Partial success	36 (17%)	22 (28%)
Failure	18 (8.5%)	10 (13%)

All values presented as mean ± SD (95% confidence interval) or number (percentage).
NPRS – Numerical pain rating scale; ODI – Oswestry Disability Index; NDI – Neck Disability Index.

Table 3
Comparison of clinical outcomes between the frequency-specific microcurrent (FSM) and control groups in low back pain and neck pain patients.

Parameters	Low back pain		Neck pain	
	FSM group	Control (Non-FSM) group	FSM group	Control (Non-FSM) group
Number of patients (n)	167	61	46	17
Mean pre-treatment NPRS	6.0 ± 1.8 (5.7–6.2)	5.8 ± 2.3 (5.2–6.3)	5.7 ± 1.9 (5.1–6.2)	5.2 ± 1.8 (4.2–6.1)
Mean post-treatment NPRS	1.1 ± 1.7 (0.8–1.3)	1.7 ± 2.1 (1.1–2.2)	1.1 ± 1.8 (0.5–1.6)	1.9 ± 2.7 (0.5–3.2)
Mean pre-treatment ODI/NDI score	46.9 ± 16.7 (44.3–49.4)	44 ± 17.1 (39.6–48.3)	34.7 ± 16.8 (29.7–39.6)	31.6 ± 14.8 (23.9–39.2)
Mean post-treatment ODI/NDI score	17.7 ± 15.8 (15.2–20.1)	21.7 ± 15.8 (17.6–25.7)	14.1 ± 11.7 (10.6–17.5)	14.6 ± 10.5 (9.2–19.9)

All values presented as mean ± SD (95% confidence interval).
NPRS – Numerical pain rating scale; ODI – Oswestry Disability Index; NDI – Neck Disability Index.

distribution of patients in NPRS categories ($p = 0.37$), and distribution of patients in disability categories ($p = 0.66$) were not significantly different when the 2 groups were compared (Table 3). Post-treatment, the mean NPRS score ($p = 0.17$) mean NDI score ($p = 0.87$), percentage of patients in the ≤3 NPRS score category ($p = 0.07$) (Table 3), and percentage of patients in the minimal disability category ($p = 0.73$) were not significantly different when the 2 groups were compared (Figs. 4 and 5). Overall, in terms of treatment outcome, there was no significant difference in the percentage of patients ($p = 1.00$) who had full success treatment outcome category when the 2 groups were compared (Fig. 3).

4. Discussion

The results of this study show that the use of adjuvant FSM therapy along with an active rehabilitation protocol significantly reduced pain and disability when compared to patients treated with active rehabilitation protocol alone for low back pain. However, the addition of FSM did not appear to significantly affect clinical outcomes of pain and disability in patients with neck pain.

The effectiveness of FSM application in patients with other musculoskeletal conditions has been previously reported in the literature (Lambert et al., 2002; Curtis et al., 2010; Kim et al., 2009; Mäenpää et al., 2004; Kwon et al., 2017). A previous study had reported that the application of FSM helped in preventing delayed onset muscle soreness (DOMS) up to 72 h post-exercise when compared to sham treatment (Curtis et al., 2010). Similarly, microcurrent electrical neuromuscular stimulation (MENS), has been reported to enhance muscle function and improve physical activity in elderly patients (Kwon et al., 2017). Furthermore, microcurrent application has been reported to be more effective than placebo or sham treatment in the treatment of musculoskeletal conditions (Maul et al., 2019; Naclerio et al., 2019; Kwon et al., 2017; Curtis et al., 2010; Koopman et al., 2009; Bertolucci and Grey, 1995) and faster acting with lower complication rate when compared to transcutaneous electric nerve stimulation (TENS) (Saranya et al., 2019; Bertolucci and Grey, 1995).

To the best of our knowledge, this is the first and the largest study in the literature to report efficacy of FSM therapy on pain and

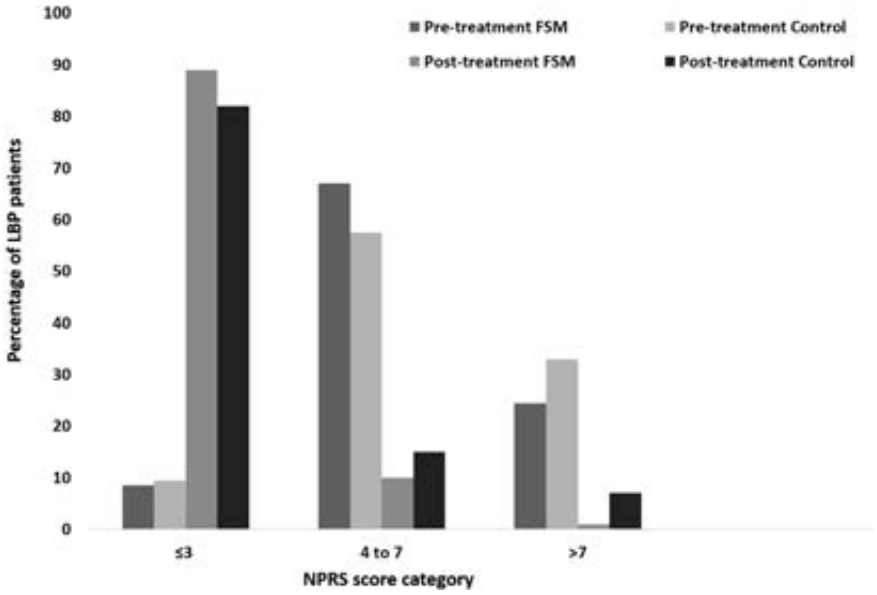

Fig. 1. Pre- and post-treatment distribution of low back pain (LBP) patients in the frequency-specific microcurrent (FSM) group and control group in the ≤3, 4 to 7 and > 7 NPRS score categories.

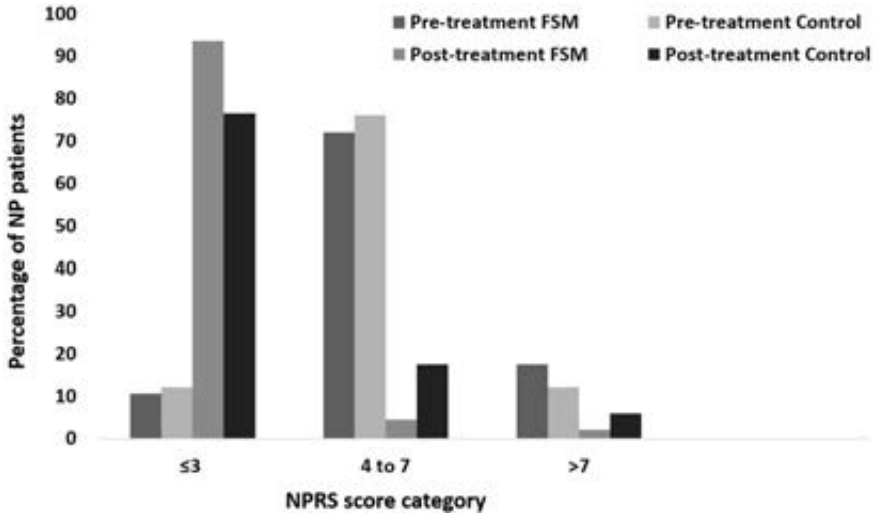

Fig. 2. Pre- and post-treatment distribution of neck pain (NP) patients in the frequency-specific microcurrent (FSM) group and control group in the ≤3, 4 to 7 and > 7 NPRS score categories.

disability in patients treated with rehabilitation therapy for low back and neck pain. In the current study, both pain intensity as measured by NPRS score and disability as measured by the ODI score was significantly better in LBP patients in the FSM group when compared to LBP patients in the control group. These findings validate similar findings previously reported by a small pilot study of 10 patients with nonspecific, chronic LBP where microcurrent application using a patch resulted in significant improvement in pain at the end of treatment (Koopman et al., 2009). In the current study, the beneficial effect of adjuvant FSM application seen in LBP patients was not seen in patients with neck pain. This could be due to the small number of patients in the NP sub-group when compared to the LBP sub-group.

Electrotherapy modalities such as TENS or interferential current, used in musculoskeletal pain, are based on the gate control theory of pain. Stimulation of peripheral sensory Aβ fibres by TENS inhibits or closes the "gate" (substantia gelatinosa) in the dorsal horn of spinal cord preventing transmission of sensory input from primary afferent neurons to the brain and inhibiting pain perception (Mokhtari et al., 2020; Moayedi and Davis, 2013). However, the clinical effect of FSM occurs at a cellular level and involves a decrease in electrical resistance, restoration of cellular homeostasis, and facilitation of tissue regeneration in contrast to TENS which primarily works by blocking the transmission of pain signals (McMakin, 2011, 2017). Hence, improvement in clinical outcomes of patients with LBP treated with FSM in the current study may be primarily due to microcurrents promoting repair and regeneration of paraspinal muscles and reducing local inflammation as previously reported in animal models (Fujiya et al., 2015). Furthermore, we used directional movements using the Mechanical Diagnosis and Therapy (MDT) technique, and strengthening and stabilization exercises as the main component of physical rehabilitation treatment in all patients with LBP or NP which most likely accounted for the significant clinical improvement after treatment. However, the results of the current study indicate that the addition of FSM as an adjuvant therapy helped achieve a better outcome in LBP patients when compared to LBP patients where FSM was not used.

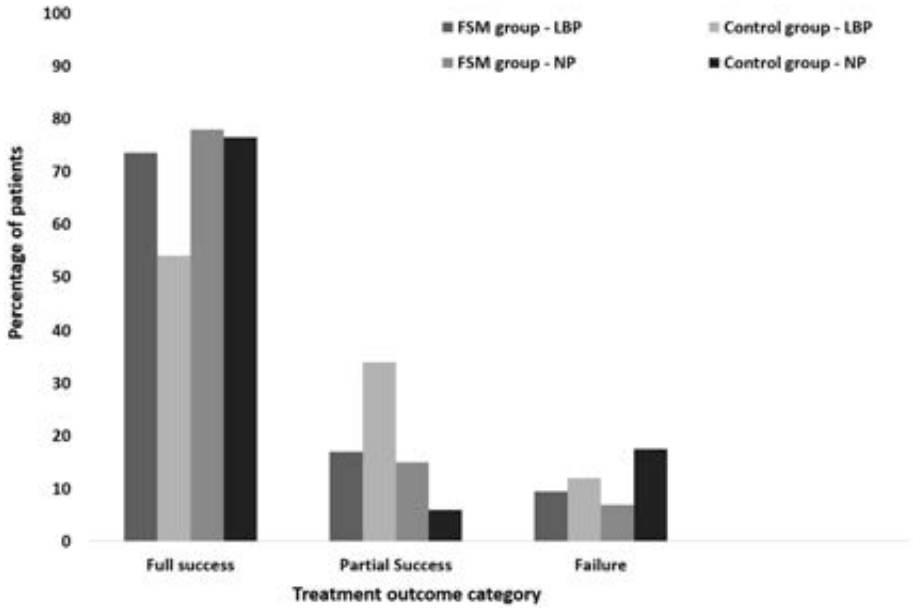

Fig. 3. Distribution of low back pain (LBP) and neck pain (NP) patients in the frequency-specific microcurrent (FSM) group and control group in full success, partial success, and failure treatment outcome categories.

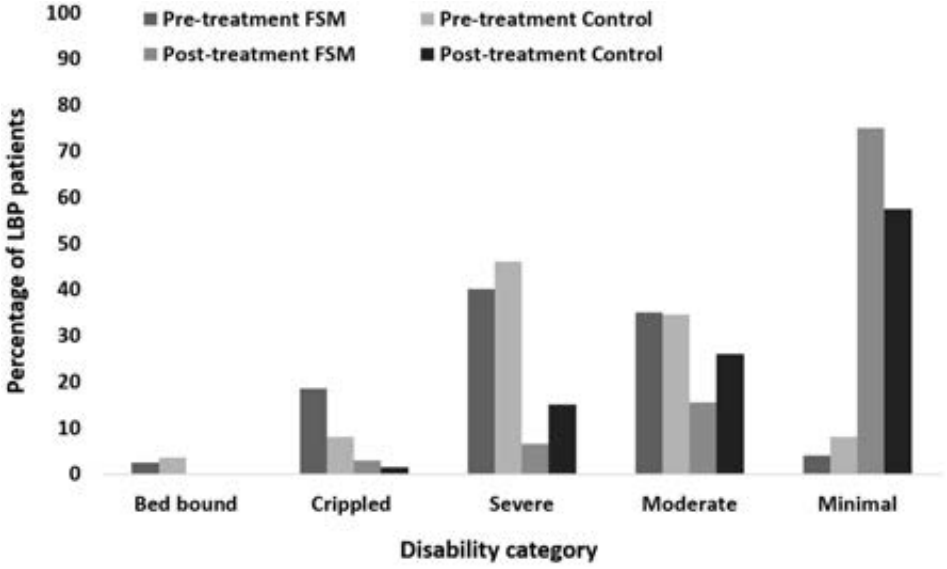

Fig. 4. Pre- and post-treatment distribution of low back pain (LBP) patients in the frequency-specific microcurrent (FSM) group and control group in the bed-bound, crippled, severe, moderate and minimal disability categories.

This study has a few limitations. First, the retrospective design of the study has its inherent biases and limitations which may affect the generalizability of the study. Second, the results reported were reported for a maximum treatment duration of 90 days. Hence the medium and long term implications of adjuvant FSM therapy in patients with LBP and NP are unknown and need further validation. Third, pain is a complex phenomenon and patient's response to physical rehabilitation treatment may be dependent on their neurophysiological and psychosocial makeup (Smeets et al., 2009; Macedo et al., 2014) which was not measured and analyzed in the current study. Hence, future studies evaluating the efficacy of FSM therapy in the treatment of LBP or NP should take into account the effect of neurophysiological and psychosocial factors on clinical outcomes. Finally, a well-designed, randomized placebo-controlled trial needs to be undertaken to further confirm the benefits of adjuvant FSM therapy as a component of conservative management of LBP and NP. However, these preliminary, encouraging results of adjuvant FSM therapy in LBP patients could form the basis for a randomized, placebo-controlled trial to investigate the efficacy of adjuvant FSM therapy in a larger number of patients with LBP and NP.

5. Conclusions

The use of adjuvant FSM application in patients treated with physical rehabilitation for low back pain significantly improved pain and disability when compared to patients where FSM was not used. Frequency specific microcurrent therapy could be a useful adjuvant in the rehabilitation treatment of patients with low back pain.

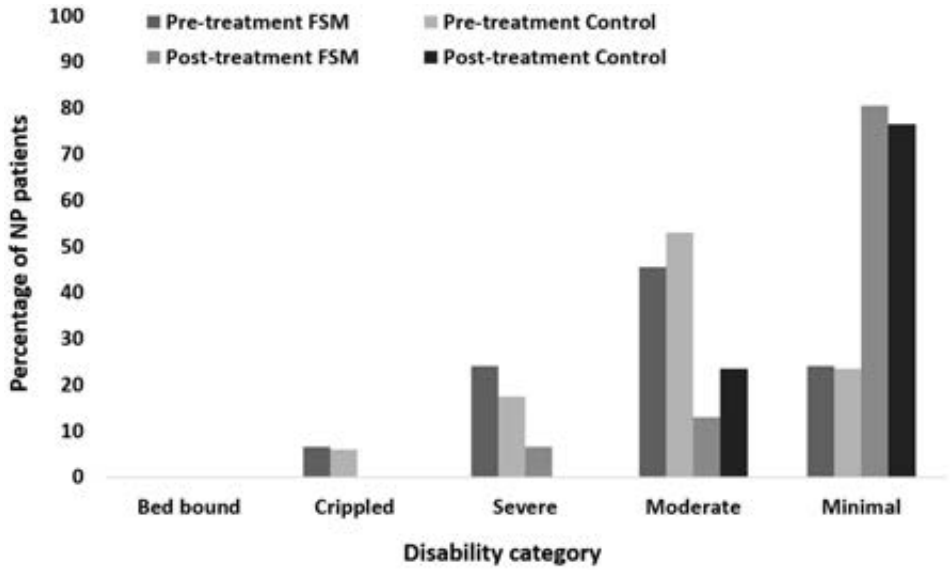

Fig. 5. Pre- and post-treatment distribution of neck pain (NP) patients in the frequency-specific microcurrent (FSM) group and control group in the bed-bound, crippled, severe, moderate and minimal disability categories.

CRediT author statement

Gautam M Shetty: Conceptualization, Methodology, Data Analysis, Manuscript writing and editing.

Pallavi Rawat: Conceptualization, Data collection and curation, Reviewing final manuscript

Anjali Sharma: Data collection and curation, Reviewing final manuscript.

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Declaration of competing interest

There are no conflicts of interest with any financial organization regarding the material discussed in the manuscript and this research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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