



Immediate Effect of Classical Five Element Acupuncture in Sciatic Pain-A Randomized Control Trial

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Abstract

Sciatica is one of the most frequently reported complaints, it affects quality of life and reduces social and economic efficacy. The prevalence of sciatic symptoms reported in the literature varies considerably ranging from 1.6% in the general population to 43% in a selected working population. Although the prognosis is good in most patients, a substantial proportion (up to 30%) continues to have pain for 1 year or longer. A number of risk factors are thought to be associated with first-time incidence of sciatica and influence the development of sciatica; these include smoking, obesity, occupational factors. Classical Five-Element Acupuncture is set apart from other methods of acupuncture by its core premise of diagnosing and treating a patient's fundamental Causative Factor: the element among the five that is the source of imbalance. The Causative Factor is assessed by way of sensory information provided by the body, mind, and spirit of the patient. Each of the elements has a corresponding odor, color, sound, and emotion, which can be perceived when a particular element is out of balance. Accurate diagnosis and treatment of the Causative Factor is the key to Classical Five-Element Acupuncture. In addition, this elegant system recognizes that the health of each unique individual's body, mind, and spirit must be taken into account to fully understand and treat the cause of illness. A prospective, randomized trial performed among 60 sciatica subjects, verified by MRI or computed tomography or SLR/ Lasegue's Test. Using simple randomization subjects were randomized under Group A (Classical; N= 30) and Group B (Sham ; N= 30) on 1:1 ratio. The Subjects of Group A and Group B received their respective treatment. Data were collected before and after treatment using 10 Point- VAS scale, and Sciatica Bothersome Index. Intensity of sciatica pain showed statistically significant improvement in Group A (P<0.001) than Group B.

KEYWORD: Sciatica, Classical Acupuncture, Sham Acupuncture, VAS, Sciatica Bothersome Index

Introduction

Sciatica is characterized by sciatic nerve pain (pain that radiates from the lowback to below the knee), paresthesia (mostly numbness and tingling), and muscle weakness in the affected leg or foot(1). These symptoms can lead to motor disabilities and mental disorders such as depression and anxiety(2). The prevalence of sciatica ranges from 1.2% to 43%(3). The most common cause of sciatica is herniation of the nucleus pulposus. Indeed, about 90% of sciatica cases are due to a herniated disc involving nerve root compression. Other possible causes include a narrow lumbar canal, foraminal stenosis, tumors, and cysts(4).

Herniated lumbar disc-related sciatica is one of the most common conditions managed in primary medical care and a significant cause of absence from work and early retirement. Patients, families, and the society at large all carry part of the burden(5). Sciatica resolves without treatment in the majority of cases. However, many patients endure substantial pain and disability(6). Medication and physical therapy are used as the initial treatment options for pain control. However, there is little evidence for the efficacy of pain medication(7). Several systematic reviews have analyzed the efficacy and safety of various drugs such as opioids and steroids, but the validity of the studies is limited(8). Furthermore, the use of pain medication has been associated with adverse effects such as sedation, dizziness, ataxia, and nausea(9). Similarly, there is little evidence for the efficacy of invasive surgeries such as lumbar discectomy and epidural steroid injections(10).

Acupuncture is a traditional Chinese medicine, which has been used clinically for more than 3000 years in East Asia. It has been described as an effective treatment approach in various diseases(11). The function of acupuncture is related to insertion of needles at specific points of the body, mentioned to as “acupoints”, which produces functional specificity(12). According to the philosophy of traditional acupuncture, energy circulates in the form of vital force called „*Qi*” or „*Chi*” through the meridian or channels located throughout the body. The yin and yang are the two aspects of the „*Qi*” energy. They function as positive and negative poles and they are corresponding to each other. Acupuncture points are alienated in several ways according to the function and location of the points. Important classifications are 12 meridian points, extra meridian points, floating or *Ah-shi* points, distal points. Meridian points are falling on the lines of the classical meridians. Extra meridian points are recently discovered and they exist mainly on the ear, hand, nose and head and some on the trunk.

Materials and Methods

A total of 60 subjects with sciatica pain, both men and women with ages ranging between 18–55 participated in the study. The study subjects were conveniently recruited from the Government Yoga and Naturopathy Medical College and Hospital, Arumbakkam, Chennai District of Tamilnadu state in India. The subjects were recruited from the above mentioned hospital through screening done to assess diagnostic criteria, inclusion and exclusion criteria. All the sixty subjects were screened through a routine medical check-up and those satisfying the diagnostic criteria for sciatica Lasegue test / SLR test were recruited.

Ethical considerations

Ethical clearance was sought from the Institutional Ethical Committee prior to the start of the study and the approval for the same was granted

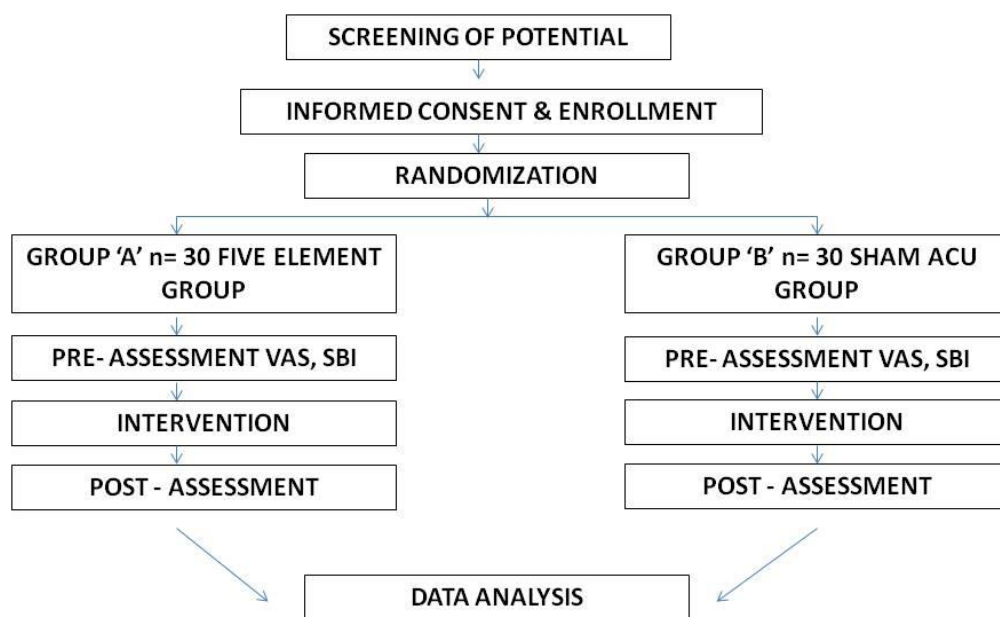
Inclusion criteria

Primary complaint of unilateral leg pain radiating below the knee. Age between 18 and 55 years (either sex). Duration of pain < 5 years. Without recent anxiolytic, sedative and/ or analgesic medication. Ipsilateral lumbar disc herniation at the corresponding level verified by MRI or computed tomography or positive SLR test and Lasegue test. Willingness and ability to accept needle- acupuncture intervention and to comply with the requirements of the study protocol. Pain intensity score of 40mm or more on a 100-mm visual analog scale (VAS)

Exclusion Criteria

Leg pain originating from the upper lumbar column (L1–L3). History of spine trauma or spine surgery. History of stroke. Heart diseases or severe hypertension, any endocrine diseases such as hyperthyroidism, and severe infection. Other therapies, especially analgesics, in the past 7 days.

Fig 15: Trial Profile



Baseline assessment:

Prior participants will be asked to fill in the visual analog scale and sciatica bothersome index before and after intervention.

Visual Analogue Scale

Level of pain intensity using validated (VAS) Visual analogue Scale for pain -100 (where 0=no pain at all; 100=maximal pain imaginable)

Bothersome sciatica index

The Sciatica Bothersomeness Index (SBI), which is a composite score of four questions (each score ranging from 0–6) that include elements of leg pain and sensory and motor disturbances, was used. Total score ranges from 0 to 24 and higher scores indicate worse symptoms.

Intervention:**Group A (Classical Acupuncture)**

In this group patient who visited our OPD with pain in the lower back with radiating to either right or left leg were treated with classical acupuncture also known as Traditional Chinese Acupuncture. Point's selection was done by "five element shu selection method". Needling was given for a period of 30 mins. VAS and SBI was given to the patient for scoring before and after needling.

Five element shu selection method:

In this method each and every symptoms presented by the patients are related with respective elements based on their characteristic features and functions. Cumulatively the major element with its yin or yang polarity, which is affected will be jotted. Further, the selected element will be matched with the 'shu group (1-5) – which is grouped according to the functions', based on this a point is selected from 60 points of command. Along with the selected point supportive points like source, xi-cleft, back-shu, front-mu points are used according to the necessity to notify the affected element. Single needle for shu point and an average of 3-5 needles for supportive points were used. The aim of classical acupuncture is to eliminate the pathogenic factor (8 factors according to acupuncture) and strengthening the affected element.

Eg: If Patient present symptoms like

- c/o back pain along left side of the leg – (back pain belongs to wood element, sides of the leg represents GB meridian)
- c/o Pulling pain around the left leg – (pulling nature represents wood element)
- c/o heaviness and numbness in the leg – (heaviness represents earth element and numbness and wood)

The majority of symptoms reveals the imbalance in the wood element and disturbance in qi flow. All the symptoms are acute and external and represents yang imbalance. Therefore GB meridian of wood element whose 5th group point from Shu table (i.e.) GB 34 is selected and needled. This corrects the imbalance among the elements. Later, to strengthen the meridian source point of GB can be given bilaterally. This approach reveals the root cause of the condition and helps to treat accurately.

Group B (Sham Acupuncture)

Sham acupuncture (SA), also called placebo acupuncture (PA), performed away from the acupuncture points established by TCM or without stimulation and manipulation to avoid eliciting "De Qi" sensations or using a non-penetrating technique, is used as control in scientific studies to determine the efficacy of acupuncture (93).

Needling:

Needling methods for both groups were same. Both groups were treated with 'use and throw' stainless steel needles. Needles with the measurement of 0.25 * 0.25 were used throughout the study. Sterile measures were adopted and used needles were carefully disposed. Needles were inserted till the level of the dermis.

Data Extraction:

Data were collected as self-reported observations using primary outcomes and secondary outcome variables. Data were obtained before and after treatment. Data were organized in Microsoft Excel sheets (version 2010)

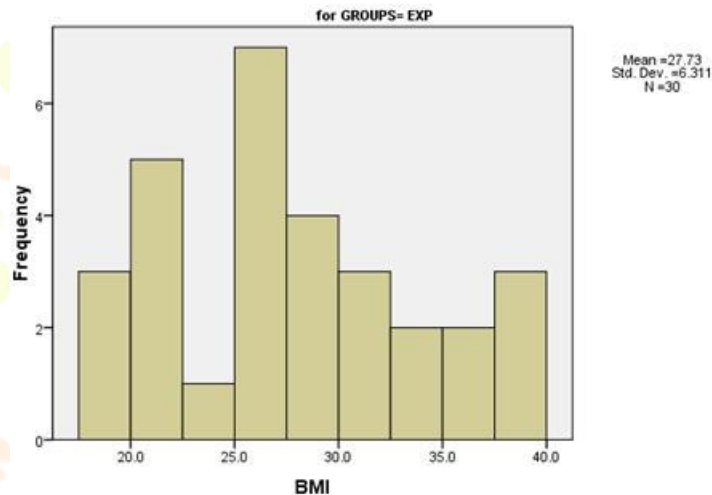
Results

The present study was conducted to evaluate the effectiveness of classical Acupuncture in Sciatic pain. The effectiveness of intervention was assessed based on the outcome variables viz 10- point VAS score, Sciatica Bothersome Index. VAS score and Sciatica Bothersome Index taken before and after treatment. The results of this study states, within group analysis showed a significant reduction of pain in the Classical Acupuncture group, whereas

in Sham Acupuncture group there is no such significant reduction of pain. None of the subjects reported any adverse events during or after Acupuncture session. Data not normally distributed tested using Kolmogorov-Smirnov and Shapiro- Wilk tests. For continuous data, the descriptive statistics were reported as mean (standard deviation). Non parametric Mann-Whitney Test was used to examine the difference between Experimental and Control.

Table 4 : Patients demographic characteristics at baseline

PARAMETERS	EXPERIMENTAL GROUP	CONTROL GROUP
	Mean \pm SD	
AGE	45.67 \pm 9.092	46.57 \pm 10.647
SBP	131.30 \pm 6.440	29.53 \pm 6.296
DBP	85.00 \pm 4.502	85.27 \pm 4.741
PR	70.45 \pm 3.094	71.10 \pm 3.791
HT	165.13 \pm 10.105	165.43 \pm 10.849
WT	72.45 \pm 14.260	70.87 \pm 17.067
BMI	26.820 \pm 5.7472	25.910 \pm 5.0657



shows the demographic characteristics such as AGE, SBP, DBP, PR, HT, WT and BMI of patients at baseline.

Table 5: Comparison of variables before and after the treatments in experimental group

Parameter	Group	N	Mean	P- Value
SBI	PRE	30	45.48	0.000
	POST	30	15.52	
VAS	PRE	30	45.45	0.000
	POST	30	15.55	

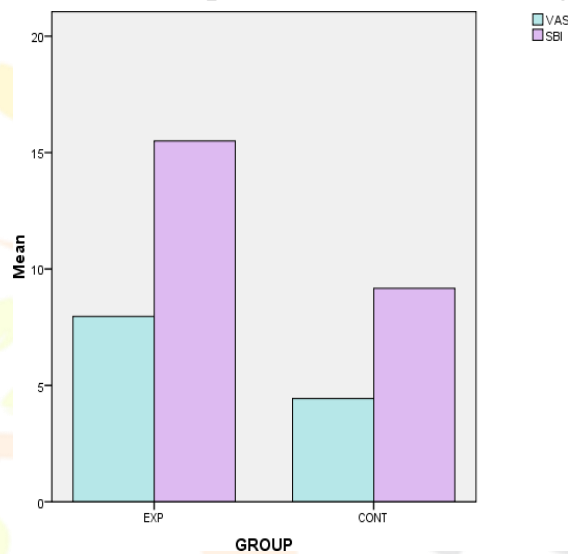
Table 6: Comparison of variables before and after the treatments in control group

PARAMETERS	GROUP	N	Mean	P- value
	PRE	30	42.47	0.000
	POST	30	18.53	
VAS	PRE	30	44.00	0.000

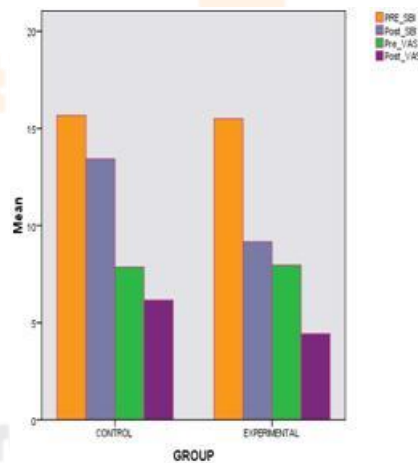
	POST	30	17.00	
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Parameters	GROUP	N	Mean	P value
PRE_ SBI	CONTROL	30	31.77	0.564
	EXPERIMENTAL	30	29.23	
Post_ SBI	CONTROL	30	44.93	0.000
	EXPERIMENTAL	30	16.07	
Pre_ VAS	CONTROL	30	29.33	0.582
	EXPERIMENTAL	30	31.67	

Comparison of mean of experimental and control group



Comparison of mean variables of control and experimental groups



Post_VAS	CONTROL	30	43.52	0.000
	EXPERIMENTAL	30	17.48	

Discussion

Sciatica is the major handicapping illness influencing the every day movement. Disregarding headway in pharmacotherapy, the same number of individuals didn't get ideal control they look for non-pharmacological methodology. Acupuncture therapy is one such methodology. In the current study, the effectiveness of classical group showed better improvement than sham group. Method adopted to treat Group A was 5 element shu selection. On reviewing prior studies on sciatica , trails were conducted using only verum acupuncture (Chinese acupuncture) with specific set of points. To my knowledge studies involving TCM diagnosis and providing individualized treatment are very few.

A study by **Jerusa A.A et al** stated “results of their pilot study used individualized treatment in real acupuncture group, seem to offer best approach.It takes into account all clinical signs and symptoms presented by each patient(94). Another study by **Facco et al** had applied TCM syndrome differentiation (a partof TCM diagnosis) to treat migraine with specific sets of points to that specific syndrome(95). Therefore in this study also TCM diagnosis and individualized treatment was given to the subjects in Group A (classical group).. Acupuncture doesn't repair a bulging or collapsed disc, but by reducing the inflammation in the area and by reducing the pain in the local and systematic pathways it is able to significantly reduce the low back and hip pain.

Acupuncture operated by releasing opioid peptides, activating the hypothalamus and pituitary gland to secrete more neurotransmitters and neurohormones and by stimulation of electromagnetic points on the body. The therapy can make the brain and spinal cord release K^+ , Ca^{++} , 5-hydroxytryptamine and opioid peptides, regulate the secretion of neuro- transmitters to block the transmission of pain, accelerate blood circulation, and promote the resorption, transfer and excretion of the above- mentioned active substances. In addition, determination of K^+ for the pain threshold may help us objectively evaluate the illness condition and the therapeutic effects, which is of significance for clinical research.(96). Acupuncture stimulates the healing process and the body to heal on its own. When the Qi energy is blocked the body can develop physical illness such as low back and hip pain. Therefore the aim of the treatment is to free the meridiansso the Qi energy can flow freely, remove all the blockages and harmonize the whole well-being(97). On the whole, patients in the classical group showed significantimprovement in the intensity of pain than sham group. The betterment was also observed in pain intensity, frequency and pain duration among classical group might be obtained due to the measures adopted to correct the root cause of disease in the patients

Conclusion

This investigation has uncovered that Classical Acupuncture is viable in diminishing the pain and related manifestation in sciatica. The traditional acupuncture has likewise indicated beneficial outcome in diminishing the recurrence and duration of pain. This investigation exhibits that the energy physiology of Classical Acupuncture is increasingly inconspicuous and needs further understanding as it is wary to execute without legitimate information. It principally targets correcting the fundamental imbalances whereupon any sickness can be dealt with successfully. On opposite over rearrangements of clinical Acupuncture however simple and powerful in conditions like help with discomfort, it has restricted the viability of Acupuncture in rectifying the major irregular characteristics.

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