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Effectiveness of Sodium Salicylate Iontophoresis on Heel Pain

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ABSTRACT: *Heel pain is one of the common musculoskeletal conditions. There are many physical therapeutic modalities including iontophoresis available for patients with heel pain. Acetate iontophoresis is commonly used for relieving heel pain. Salicylate iontophoresis is known for its analgesic and anti-inflammatory effect. However there is a paucity of data on effectiveness of sodium salicylate iontophoresis on heel pain. The purpose of this study was to evaluate the effectiveness of salicylate iontophoresis on heel pain and to compare it with acetate iontophoresis. Sixty patients with heel pain aged 25-40 years were included in the study and were randomly divided into 2 groups containing 30 patients each. Patients in group A (control group) were treated with acetic acid iontophoresis and in group B (experimental group) were treated with sodium salicylate iontophoresis. All patients received 6 sessions of iontophoresis over the period of 2 weeks. Pain on VAS and TUG test was assessed pre intervention, at the end of 2 weeks and 4 weeks. On statistical analysis, group B patients had statistically significant improvement in pain on VAS ($p<0.001$) as compared to group A. There was no statistically significant difference in TUGT ($p<0.001$) between the two groups. This study concludes that sodium salicylate iontophoresis was more effective in reducing heel pain.*

Keywords*: Iontophoresis,sodium salicylate,acetic acid,heel pain,VAS,TUG test*

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I. Introduction:

Heel pain is one of the common complaints and it is estimated that 1 in 10 people develop heel pain in their life time. Approximately 2 million people receive treatment every year for this condition[1, 2]. Heel pain can be treated using various modalitilties , iontophoresis being one of them.

Acetic acid, sodium salicylate, lidocaine, dexamethasone, magnesium sulphate etc are the commonly used ions for iontophoresis[7,8]. Acetate iontophoresis is commonly used for relieving heel pain. Salicylate iontophoresis is known for its analgesic and anti-inflammatory effect and is used in various conditions like osteoarthritis of knee. However to the best of our knowledge there is a paucity of data on effectiveness of sodium salicylate iontophoresis on heel pain. Therefore the purpose of this study was to investigate the effectiveness of salicylate iontophoresis on heel pain and to compare it with acetate iontophoresis.

II. Material And Methods :

This was a randomized controlled trial and was carried out on patients of department of physiotherapy at K.J.Somaiya college of physiotherapy, Mumbai. A total of 60 patients (both male and female) with heel pain of age 25-40 years were included in the study.

Study design: Randomized control trial
Study Location: It was carried out at the physiotherapy department of K.J.Somaiya college of physiotherapy, Mumbai.
Study Duration: 18 months
Sample size: 60 patients with heel pain
Subjects and selection method: Convenience sampling with random allocation.
Inclusion criteria:
1) Males and females diagnosed with heel pain
2) Age: 25 to 40 years
3) Pain on Visual analogue scale ≥ 6
Exclusion criteria:
1) Patients with known allergies to acetic acid
2) Patients with known allergies to sodium salicylate

3) Patients with a recent history of metabolic, endocrine, rheumatic or infective diseases
4) Patients with a recent history of malignant or neurological conditions
5) Patients with a recent history of any surgery and/or trauma of lower limb.

Procedure methodology:. All the patients with heel pain who fulfilled the inclusion criteria and were willing to participate were included in the study. A total of 60 patients were taken for the study. Written consent was obtained. Basic information was recorded, visual analog scale and timed up and go test was administered and documented in the case record form. They were then allocated either to group A or group B by computer generated random allocation method.30 patients in each group.
Patients in group A (control group) were treated with acetic acid iontophoresis and in group B (experimental group) were treated with sodium salicylate iontophoresis, with conventional therapy common in both the groups as stretching for gastrocnemius, soleus and plantar fascia, strengthening exercises for intrinsic muscles of the foot, ergonomic advice, footwear modifications as required [13,27,28,29.]

All patients received 6 sessions of iontophoresis over the period of 2 weeks at regular interval. Pain on VAS and TUG test was assessed pre intervention, at the end of 2 weeks and 4 weeks.All the patients were prescribed a non-steroidal anti inflammatory drugs and an antacid for 5 days by an orthopaedic surgeon.

Patient position: Patients were asked to lie prone with their feet out of the plinth so as to attain a neutral position of the ankle. Once comfortable, maximum painful area was located and marked on the heel by the examiner. A gauze uniformly moistened with the solution was kept under active electrode i.e., cathode and was secured with straps over the most painful area of the affected heel. Lint pad uniformly moistened with plain tap water was kept under indifferent or dispersive electrode i.e., the anode and was secured with straps a few inches away on the bulk of gastrocnemius muscle. Gauze under the delivery electrode was 1 cm thick and 1 cm wider than the electrode. Cathode was bigger than the anode to decrease the current density. Lint pad used under the dispersive electrode was of 8 folds and 16 layers.
Application of iontophoresis: 2% acetic acid was used for group A patients and 2% sodium salicylate for group B patients. Current intensity of 4 mA was applied. Each session lasted for 10 minutes. The treatment dosage did not exceed the maximum recommended dosage of 40mA.min [7,8,30] .

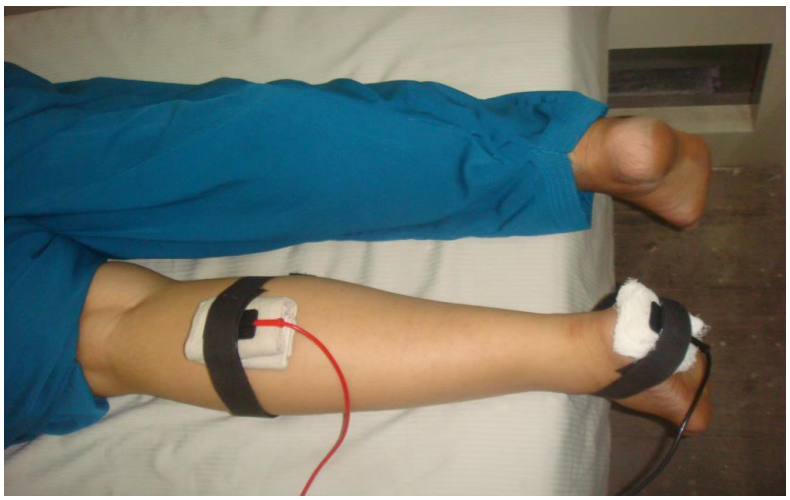


Fig. 1

Statistical analysis: The data obtained was entered using MS-Excel-2007 and statistically analysed using SPSS-20 software.Parametric test was used wherever the data passed the test of normality and non parametric test was used wherever the data did not pass the test for normality**.**
Repeated measures ANOVA test was used for comparison within the group (For comparison of mean of variable recorded at 0 week, 2 weeks & 4 weeks).
Mann-Whitney U test was used for the comparison of mean between two groups.
The p value less than 0.05 was taken as statistically significant.

III. Results :

60 patients with heel pain were enrolled for the study,30 in each group. Out of which 28 were males and the remaining 32 were females. Group A consisted of 13 males and 17 females, Group B consisted of 15 males and 15 females.

The age ranged between 25-40years. Mean age of group A was 33.27 ± 3.93 years and mean age of group B was 32.57 ± 4.15 years.

Table 1A: Comparison of visual analog scale within the groups.

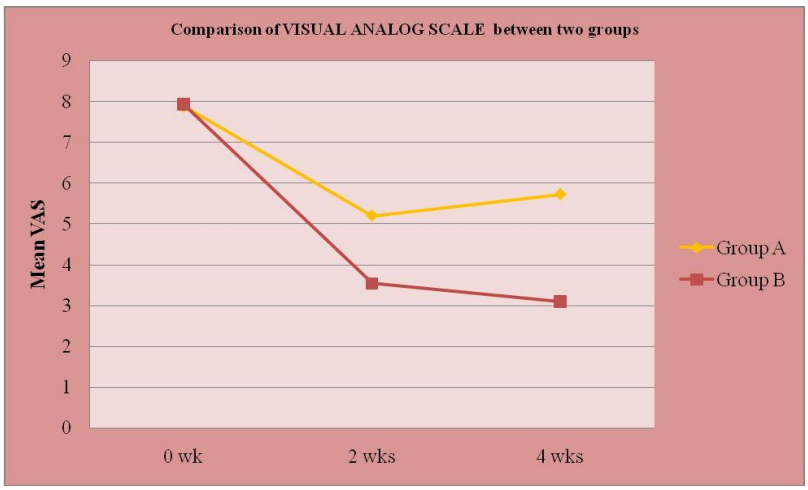
VAS		Mean	Std. deviation	N	P value	Significance
Group A	0 wk	7.887	0.9519	30	---------	---------
	2 wk	5.200	1.4655	30	< 0.001	Significant
	4 wk	5.727	1.6178	30	< 0.001	Significant
Group B	0 wk	7.937	1.1601	30	----------	---------
	2 wk	3.543	1.5869	30	< 0.001	Significant
	4 wk	3.097	1.8110	30	< 0.001	Significant

INFERENCE: The above table shows significant reduction in pain in both the groups at 0 to 2 and 0 to 4 weeks on visual analog scale.

Table 1B: Comparison of visual analog scale between the two groups

VAS	Group	N	Mean	Std. deviation	P value	Significance
0 wk	Group A	30	7.887	0.9519	0.857	Not significant
	Group B	30	7.937	1.1601		
2 wks	Group A	30	5.200	1.4655	0.001	Significant
	Group B	30	3.543	1.5869		
4 wks	Group A	30	5.727	1.6178	0.00	Significant
	Group B	30	3.097	1.8110		

GRAPH 1:



INFERENCE: The above graph shows a statistical significant improvement in pain on VAS in the experimental group (group B) as compared to control group (group A).

Table 2A: Comparison of timed up and go test within the groups

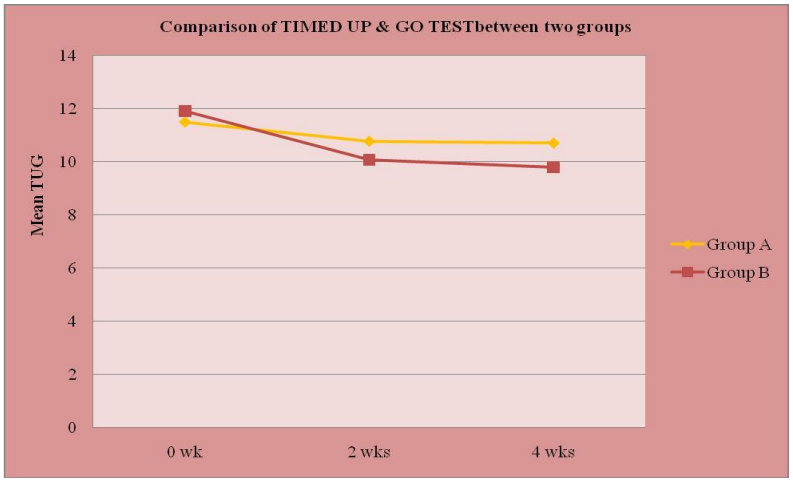
TUGT		Mean	Std. deviation	N	P value	Significance
Group A	0 wk	11.50	2.113	30	---------	---------
	2 wk	10.77	2.223	30	< 0.001	Significant
	4 wk	10.70	2.136	30	< 0.001	Significant
Group B	0 wk	11.90	1.863	30	----------	---------
	2 wk	10.07	1.617	30	< 0.001	Significant
	4 wk	9.80	1.690	30	< 0.001	Significant

INFERENCE: The above table shows statistical significant reduction in time in both the groups at 0 to 2 and 0 to 4 weeks on timed up and go test.

Table 2B: Comparison of timed up and go test between the two groups

TUGT	Group	N	Mean	Std. deviation	P value	Significance
0 wk	Group A	30	11.50	2.113		
	Group B	30	11.90	1.863	0.483	Not significant
2 wks	Group A	30	10.77	2.223	0.199	Not Significant
	Group B	30	10.07	1.617		
4 wks	Group A	30	10.70	2.136		Not Significant
	Group B	30	9.80	1.690	0.112	

GRAPH 2:



INFERENCE: The above graph shows there was no significant difference in reduction of time on TUG test between the experimental group (group B) and control group (group A).

IV. DISCUSSION: Heel pain is characterised by an insidious, sharp pain; progressive in nature; usually worst in the morning or after a period of rest like sitting or sleeping. If ignored, the pain becomes severe and significantly impacts a person's daily routine causing a negative impact on the general health related quality of life[9]. Most common causes of heel pain are tight Achilles tendon, weak foot muscles, incorrect foot wear, tendinitis etc [5,15]. Therefore improvements in the strength of weak foot muscles, decreasing stiffness along with reduction in the pain are important components of treatment.

The purpose of this study was to investigate the effectiveness of salicylate iontophoresis on heel pain and to compare it with acetate iontophoresis.

After screening for the inclusion criteria, a total of 60 patients were enrolled for the study. It was observed that out of the total sample of 60 patients there were 28 males and 32 females. They were divided into two groups by computer generated random allocation list. Group A was control group and Group B was experimental group. The control group received acetic acid iontophoresis and experimental group received sodium salicylate iontophoresis. Standard exercises like plantar fascia stretching, gastrocnemius stretching, soleus stretching and strengthening of intrinsic foot muscles being common in both the groups.

Visual analog scale and timed up and go test (TUGT) were used as an outcome measures at 0 week, 2 weeks of treatment and at 4 weeks of follow-up. Results were obtained and statistical analysis was done.

The results of the study were as follows:

- There was statistically significant decrease in pain and improvement in function indicating improvement in patients treated with acetic acid iontophoresis and sodium salicylate iontophoresis.
- At 2 weeks of intervention both the groups showed statistically significant improvement in pain and function as compared to the pre treatment values.
- At 4 weeks follow-up, the changes were statistically significant as compared to the pre-treatment values in both the groups.
- Visual analog scale score was found to be significantly better in group B (sodium salicylate iontophoresis) than group A (acetic acid iontophoresis).

VISUAL ANALOG SCALE:

Comparison within the group:

As evident from table 1A for group A and for group B, this study showed statistically significant improvement of pain in both group A ($p<0.001$) and group B ($p<0.001$).

In group A acetic acid 2% iontophoresis was used which might have helped in relieving pain. Similar findings were observed by **H R Osborne and Allison G T (June 2006)[14]; Japour CJ et al (May 1999)[12]; Gard K and Ebaugh D (December 2010)[22]; Weider DL (February 1992)[23]** in their study that stated an improvement in pain with acetic acid iontophoresis.

The improvement in group A can be attributed to the mechanism of acetic acid iontophoresis. The physiological response to a tissue which is chronically inflamed results in high concentrations of insoluble calcium carbonate to the injured area, contributing to the ongoing pain cycle and abnormal restructuring of myofascial tissue. Acetate ions in acetic acid solution once subdermal combine with the calcium ions in calcium carbonate and form soluble calcium acetate. This is then dissolved within local blood circulation and is removed from the site of injury thus breaking the pain-inflammation cycle and causing pain relief[13,26]. Acetate also helps dissolve scar tissue and calcific deposits in soft tissue[10].

$CaCO_3 + 2H(C_2H_3O_2) = Ca(C_2H_3O_2)^2 + H_2O + CO_2$

The pain improvement in group B can be attributed to the mechanism of sodium salicylate iontophoresis. Sodium salicylate is known for its analgesic and anti-inflammatory actions. The cathodic iontophoresis of salicylate results in local transcutaneous tissue permeation to the superficial muscle causing salicylate to reach deeper tissue structures below the application site. Once sub dermal the salicylate ions inhibit the cyclooxygenase (COX-2) involved in the production of prostaglandin which is a potent pain mediator[11] and thus brings about the analgesic effect.

The intraosseous pressure resulted from oedema which is formed during the process of inflammation is also reduced by sodium salicylate[11]. Also the improvement of pain and inflammation was observed by **Aiyejusunle CB et al (March 2007) [11]; Odebiyi DO et al (April 2007) [20]; Soroko YT et al (December 2002) [21].**

Comparison between two groups:

After comparing the two groups as evident from table 1B, this study showed statistically significant improvement in pain in group B with sodium salicylate iontophoresis ($p<0.001$) compared to group A with acetic acid iontophoresis Thus rejecting the null hypothesis.

This can be attributed to the analgesic and anti-inflammatory action of sodium salicylate[11] compared to acetic acid which only dissolves the scar tissue[10] and calcium ions present in chronically inflamed tissue [13].

TIMED UP AND GO TEST:

Comparison within the group:

As evident from table 2A for group A and for group B, this study showed statistically significant improvement in timed up and go test in both group A ($p<0.001$) and group B ($p<0.001$). This improvement can be attributed to the stretching program for gastrocnemius, soleus and plantar fascia.

Kibler and colleagues[24] found reduction in muscle strength and flexibility in majority of the patients with plantar fasciitis.

Tight Achilles tendon which limits the ankle dorsiflexion leads to excessive pronation stretching the plantar fascia abnormally. This abnormal tension created in plantar fascia by biomechanical factors may be subclinical unless other factors of overload like running, improper shoes, obesity, sudden increase in activity, prolonged standing or walking occur [25]. Stretching can be helpful in reducing tension and contractures that contribute to heel pain[3].

Except for iontophoresis both the groups received stretching for gastrocnemius muscle, soleus muscle and plantar fascia; strengthening exercise for intrinsic foot muscles. Also the subjects were advised to perform plantar fascia stretching in the morning or after a period of rest before starting any activity. This also reduced the pain.

Digiovanni BF et al (August 2006)[19]; Drake M et al (April 2011)[17]; Hyland MR et al (June 2006) [6]; Cleland JA et al (August 2009)[16]; Renan-Ordine R et al (2011)[4]; Joel A Radford et al (April 2007)[18]; Costa IA et al (2007)[13] in their studies found that stretching of plantar fascia, gastrocnemius muscle, soleus muscle and strengthening exercise to the intrinsic foot muscle had a short term as well as long term improvement in pain and function in patients with heel pain; this is similar to the results of this study which also shows an improvement in the pain and function.

Comparison between two groups:

After comparing the two groups as evident from table 2B, this study did not show significant improvement ($p<0.001$) in the timed up and go test.

In this study, there was a significant improvement seen in pain and function in group B with sodium salicylate iontophoresis.

IV. Conclusion:

The study showed that sodium salicylate iontophoresis was more effective in reducing pain and improving function in patients with heel pain compared to acetic acid iontophoresis.

1. Limitation**:** 1.Small sample size,2.The results of the study cannot be generalized to the population, as the sample was randomly assigned from a single tertiary hospital.,3.Presence or absence of calcaneal spur was not investigated.

2.Recommendation: The study may be carried out on a large sample size for longer duration to determine the carry over effect of sodium salicylate iontophoresis.

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