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A Comparative Study to Know the Effect of Diclofenac Sodium Iontophoresis and Methyl Salicylate Iontophoresis on Pain, Range of Motion and Disability among Patients with Frozen Shoulder

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Abstract

Objectives: *This study aimed to compare the effect of diclofenac iontophoresis and methyl salicylate iontophoresis on pain, disability and range of motion among patients with frozen shoulder.*
Background: *Frozen shoulder is a condition characterized by gradual loss of active and passive range of motion along with pain. In the past along with various conservative treatment including medicine other physical treatment, Iontophoresis using diclofenac, methyl salicylate along with active exercises has been effectively used. Literature lacks regarding the comparison of diclofenac and methyl salicylate iontophoresis along with exercise for treatment of frozen shoulder.*
Methodology: *The study included 45 subjects both male & female which were equally divided into three groups, 15 subjects in each group. GROUP C served as (Control group) received short wave diathermy, Transcutaneous Electrical Nerve Stimulation and exercises, this combination serve as baseline treatment. GROUP A (Experimental group) received baseline treatment along with diclofenac iontophoresis and GROUP B (Experimental group) received Methyl Salicylate iontophoresis and base treatment for 5 days a week for 2 weeks.*
Result: *Within groups analysis pre and post showed significant improvement in VAS, SPADI and Range of motion in all the groups. Whereas, in between group analysis showed no significant difference for VAS, SPADI & ROM except Group B (Methyl salicylate) showed significant improvement in flexion ROM in comparison to group C (Control group).*
Conclusion: *SWD, TENS and exercise with or without iontophoresis can be used for the improvement of pain, disability and ROM among frozen shoulder patients. Iontophoresis did not have any additional benefits.*

Keywords: *Iontophoresis, Methyl salicylate, Diclofenac, Shoulder disability, Passive range of motion, Shoulder pain.*

Introduction

Frozen shoulder is a multifactorial soft tissue disorder also called adhesive capsulitis. It is self-limiting characterized by inflammatory dense adhesions, thickening and restriction of the glenohumeral capsule expansion, which causes pain with gradual restriction of active and passive movements of the shoulder joint, in a capsular pattern[1]. Frozen shoulder is commonly seen in middle-aged individuals, with an insidious onset between 40 - 70 years of age with an average age of 50 years[2], females are more affected than males, left shoulder is more often involved than the right. The following factors put the individual at risk for the development of frozen shoulder like diabetes[3], stroke[4], thyroid[5], trauma, prolonged immobilization, myocardial infarction and autoimmune diseases. Based on the mechanism of onset, there are two types of frozen shoulder.

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Primary or Idiopathic cause of which is not known, mainly seen in females above 45 of age. The second one is secondary frozen shoulder caused as a consequence of some underlying conditions, like diabetes mellitus, trauma, prolonged immobilization of the upper limb. Histologic studies of adhesive capsulitis provide insight into its cellular and molecular pathogenesis, emphasizing the role of fibrosis and altered tissue remodeling in its pathogenesis, fibroblasts, and myofibroblasts. Frozen shoulder is typically characterized by pain that is exacerbated by shoulder movement and improved by rest. Patients often experience increasing pain, especially at night, which can interfere with sleep and as the condition progresses; there is a marked decrease in the ability to perform daily activities. The natural progression of frozen shoulder occurs in three clinical stages[6]. **Stage 1**: Freezing (2 to 9 months) shoulder pain during both rest and activity. Night time discomfort is particularly intense due to the stretching of the capsule, which can disrupt sleep, **Stage 2:** Frozen or transitional (4 to 12 months) stiffness and

restricted movement become more prominent. Pain may still occur at the end of the range of motion (ROM), but eventually, some people may report little to no pain, even at the limits of movement, **Stage 3:** Thawing / Recovery stage (5-24 months) thawing stage is marked by a reduction or complete absence of pain, along with a slow and steady improvement in shoulder joint movement.

A Wide range of conservative and surgical treatment approaches were used to manage frozen shoulder effectively. Conservative treatment including, patient education oral nonsteroidal anti-inflammatory drug (NSAIDs)[7], topical application of NSAIDS, Physical therapy, including ROM exercises[8], strengthening exercises[9], capsular stretching, exercise through a limited arc and use of various modalities like SWD, ultrasound, TENS, phonophoresis & iontophoresis[10]. In Iontophoresis, direct current is used to enhance the penetration of ionic agents and thus aid in better transport and absorption to produce better therapeutic effect[11]. During topical application skin possesses a lipophilic nature poses an obstruction to transdermal delivery of drugs, and the drug penetrates up to 3-4mm[12] whereas with Iontophoresis its depth of penetration increases various ions used for shoulder pain found to be effective one as Diclofenac sodium, Ibuprofen, Iodine, Methyl salicylate and Naproxen. Literature lacks regarding the comparison of diclofenac and methyl salicylate iontophoresis as a treatment modality for frozen shoulder.

So, aim of this study was to compare the effect of diclofenac iontophoresis and methyl salicylate iontophoresis on pain, disability, and range of motion among patients with frozen shoulder.

Methodology

Subject: Pre diagnosed patients of frozen shoulder reported to OPD of institute & other approved hospitals. Both genders aged between 40 to 60 were taken for the study. A total of 63 subjects reported in the department with shoulder pain and stiffness were screened and examined and those who met inclusion criteria or exclusion criteria. A total of 45 subjects were incorporated for analysis.

Procedure: All subjects reported in the department with shoulder pain and stiffness were screened and examined. After assessing the subjects, 11 subjects were excluded, and 7 subjects dropped out during their ongoing study. A written informed consent was obtained from all the subjects. A minimum of 45 subjects were selected for the study and were divided equally into three groups,15 subjects in each group, i.e., group “A”, group “B”, and group “C”. GROUP C served as the control group. received short-wave diathermy, transcutaneous electrical nerve stimulation, and exercises. Intervention was given for 2 weeks, 5 times a week. GROUP A (Experimental group) received diclofenac iontophoresis, short wave diathermy, transcutaneous electrical nerve stimulation, and exercises, GROUP B (Experimental group) received Methyl Salicylate iontophoresis, short wave diathermy, Transcutaneous electrical nerve stimulation, and exercises. Intervention was given for 2 weeks, 5 times a week. Data was recorded on pre-treatment at 1st day, post intervention on 5th day and post-intervention on 10th day for VAS, SPADI, and ROM.

Protocol

Diclofenac Iontophoresis - For Diclofenac Iontophoresis subjects were in supine position. Voveran Emulgel by dr. Reddy’s Laboratories which contains 1.16% diclofenac massaged on the most painful region of the shoulder. Negative electrode of size 3x2.5 in covered with soaked lint cloth was placed over massaged area. Second passive anode electrode with sizes of 1.5 x 2.5 inches. Direct current was utilized for 25 min with intensity of 4mA was applied[13].

Short-Wave diathermy- Subjects were asked to lie in comfortable position and SWD was applied to a subject lying in supine using pad electrodes on the patient’s shoulder using a contra-planar method for 20 min[14].

Transcutaneous electrical nerve stimulation (TENS): TENS was applied with frequency of 150Hz and intensity according to patient’s comfort for 15minutes[15].

Methyl Salicylate -Meftal forte, which contains methyl salicylate 30% massaged on the most painful region of the shoulder. A customized electrode made of heavy-duty silver foil was used. Direct current was utilized for 20 min with an intensity of 2mA[16,17].

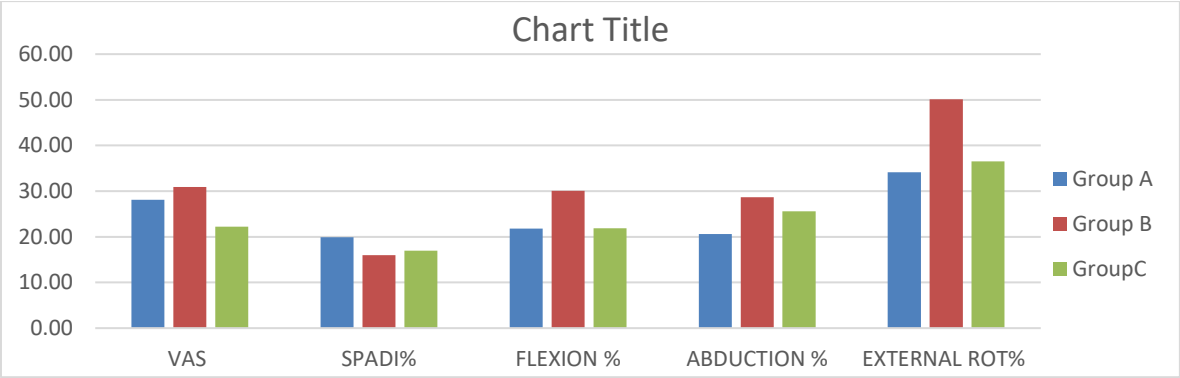
Exercise Protocol- Three Exercises were given to each subject: Pendulum Exercise, Stick Exercise, and Wall ladder. Pendulum Exercises[18]. Performed by leaning forward and letting the arm dangle, then gently moving it in small circles. Wand Exercises[19]: Elbows at the sides, bent to 90°, wand held horizontally. The unaffected arm pushes the wand laterally the affected extremity is rotated away from the body. Wall ladder[18].Subject facing the wall, affected shoulder one arm distance to the wall so that only fingers can just touch wall and walk the fingers of the affected arm up the wall as high until they felt a stretch. It was repeated for 10 repetitions. Data was recorded on pre-treatment at 1st day, during intervention on 5th day, and post-intervention on 10th day for pain using a visual analogue scale (VAS), disability is calculated by SPADI, and Range of motion of the shoulder measured with universal goniometry.

Result: To summarize the result, all the interventions were effective in improving shoulder pain (VAS), Disability & ROM in first week and over a period of 2 weeks in all the groups (Table no 1). In between group comparison shows that all the groups were equally benefitted as no significant difference were observed except flexion ROM (Table no 2) which was increased significantly in Group B (Methyl salicylate) in comparison to group C (Control group).

Table No 1 Showing Mean & SD and analysis of repeated measures for visual analogue scale (VAS), Shoulder Pain and Disability Index (SPADI), Active Shoulder Flexion range, Abduction & External Rotation ROM within group.

	Day 1 &Mean & SD	Day 5 & Mean & SD	Day 10 & Mean & SD	F-Value	P -value
GROUP A					
VAS (mm)	82.40±5.24	68.13±11.0	54.25±11.8	89.54	*<0.001
SPADI %	65.88±6.63	55.46±8.34	48.00±13.6	45.82	*<0.001
Flexion	99.330±18.9	109.00±199	121.00±19.6	19.65	*<0.001
Abduction	80.000±15.1	90.53±20.8	101.25±20.2	35.41	*<0.001
External Rotation	19.530±5.20	23.93±5.36	26.20±5.66	51.53	*<0.001
GROUP B					
VAS (mm)	83.45± 8.09	51.20±13.15	55.65±11.84	85.13	*<0.001
SPADI (%)	52.53±5.14	63.35±6.654	54.55±5.31	56.84	*<0.001
Flexion	103.00±16.80	116.45±15.524	134.0±12.2	81.55	*<0.001
Abduction	81.13±16.49	91.53±15.088	104.4±11.5	48.38	*<0.001
External Rotation	16.330±5.81	21.25±5.235	25.0±8.01	45.32	*<0.001
GROUP C					
VAS (mm)	82.29±9.34	54.55±11.65	64.00±13.89	30.28	*<0.001
SPADI (%)	65.52±8.35	60.31±5.08	50.58±5.94	65.66	*<0.001
Flexion	95.500±19.54	106.29±19.69	116.36±21.18	46.06	*<0.001
Abduction	53.050±15.38	59.50±15.60	93.36±18.84	32.20	*<0.001
External Rotation	15.500±5.41	21.00±5.23	23.93± 5.41	56.59	*<0.001

In between group analysis for flexion (degrees) indicated that there was significant difference in flexion ROM on day 10 with a F value of 3.53 & p-value (0.032). On further analysis using Turkey's pairwise comparison these was more improvement in group B (30.1%) than group C (21.84%) significantly.



Discussion

Aim of the study was to compare the effect of diclofenac iontophoresis and methyl salicylateiontophoresis on pain, disability and range of motion among patients with frozen shoulder. All the interventions were effective in improving shoulder pain (VAS), Disability & ROM in first week and over a period of 2 weeks in all the groups. In between group comparison shows that all the groups were equally benefitted as no significant difference were observed except flexion ROM which was increased significantly in Group B (Methyl salicylate) in comparison to group C (Control group).

In this study control group (Group C) showed a significant decrease in VAS score by 22.22% over a period of two weeks. Similarly, Hague A et al[20] reported a 25.65% improvement in VAS after 2 weeks intervention with Short Wave Diathermy (SWD), NSAIDS & Exercises (Codman, wall climbing & wand exercises). VAS score was also decreased by 28.14% over two weeks InGroup A similar results were also as reported by Vecchini et[13] al with diclofenac iontophoresis in scapula-humeral periarthritis. In current study Group B (Methyl Salicylate) showed significant improvement in VAS score by 30.90% over a period for two weeks. Whereas higher improvement (60.46%) in VAS scores was reported by Bumin G et al[17] after 10 sessions of interventions using methyl salicylate Iontophoresis, Short wave diathermy and Exercises. In current study pain could have decreased due to the therapeutical effect of SWD, TENS and Exercises in all the groups. Short wave diathermy could have increased the temperature around the shoulder, led to the vasodilation & increased blood flow

which facilitated removal of inflammatory products and so decrease in pain it could have also improves supply of nutrients and oxygen and helped in removal of muscle spasm and so pain & increases ROM. High TENS could have resulted in the stimulation of large diameter Aß mechanoreceptors and could have blocked pain fibers from carrying pain through pre-synaptic inhibition. Benefits derived from targeted exercises could be due to enhanced delivery of nutrients[1] to the joint, facilitate inflammatory waste product removal from the shoulder and thereby potentially diminishing inflammation and improving pain levels & minimizing muscle guarding and spasms. Diclofenac sodium Iontophoresis could have also contributed in the modulation of pain by its anti-inflammatory effect through the inhibition of inflammatory mediators like prostaglandin[23.] Methyl salicylate is thought to function through its analgesic, anti-inflammatory effects & so could have caused vasodilation of blood vessels, in improved blood flow so removal of inflammation & inhalation of pain.

In this study there was a statistically significant improvement of ROM within groups over a period of two weeks with 20.59% least gain in group A abduction ROM or to maximum gain of 50% in group B external rotation (Table No 1). Similarly, improvement was observed in various ranges in their previous studies[15,19] with similar interventions to our control group. Vecchini L & Grossi[13] E also reported an improvement in terms of functional impairment for ROM with diclofenac iontophoresis. Increased temperature by SWD could have led to the Collagen extensibility by easy deformation of collagen fibers and so gain in range of motion. Further SWD could have helps in removal of muscle spasm and decrease in pain could have also in gain in ROM. We assume that high TENS could have decreased pain, spasm and swelling and led to gain in ROM as also reported for the knee joint with the use of high TENS22. Griggs et al[21] reported exercises could have decrease pain & spasm which might have contributed in gain in ROM.

Improvement in ROM observed in experimental group B could be attributed to the synergistic effects of the initial treatments (SWD, TENS, and exercises) combined with the iontophoresis of methyl salicylate. Methyl salicylate could have also contributed by inducing vasodilation which results in improved blood flow which might have decreased spasm around the shoulder and could have contributed to increased ROM24. Diclofenac sodium Iontophoresis could have also contributed in the modulation of pain by its anti-inflammatory effect through the inhibition of inflammatory mediators like prostaglandin[23].

Regarding disabilities a significant improvement in SPADI score by 16.94%, 19.88%, 17.96 % in group C, group A and group B respectively were observed within groups, similarly Haque A et al reported a 17.27% improvement in disability with short wave diathermy, exercise, and NSAIDs. In this study it was observed that there was significant improvement in pain as discussed earlier so it could have contributed for the improvement of disability among all the groups, as pain is the major component of SPADI. Authors are unaware of any study in which disability could have been used an outcome measure along with iontophoresis. So, authors are in view of that the improvement in disability in group A could have also been due to therapeutic effects of diclofenac sodium iontophoresis as reported lateral epicondylitis and methyl salicylate in group B as reported earlier for along with the effects modalities by SWD, TENS & Exercises.

In current study no significant differences were observed in between groups except flexion ROM in group B (30.1%) in comparison to group C (21.84 %) significantly. Authors assume that more improvement in pain in group B (30.9%) in comparison to group C (22.22%) could have been contributed to more gain in group B ROM.

Conclusion

The result of this study reveals that within group analysis showed significant improvement inVAS, SPADI and Range of motion of shoulder joint. With SWD, TENS and Exercises (Group C), diclofenac sodium along with baseline treatment (Group A) and methyl salicylate iontophoresis (Group B) where effective among frozen shoulder patients whereas in between group analysis showed that no significant improvement except methyl salicylate which showed significant improvement in flexion ROM in comparison to group C. So it is observed no additive effect could be achieve with iontophoresis among frozen shoulder patients with 2 weeks of intervention.

Future Scope

The study will aid in the literature as baseline and also this study will aid in future studies. Thesame interventions can be experimented on other joints or pathologies. These interventioncombinations (SWD, TENS, Exercises along with/without Methyl salicylate & Diclofenac sodium)can be effectively used in reducing pain, disability and ROM among patients of frozen shoulder.

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