



Research Article

## CLINICAL TRIAL TO DEVELOP AYURVED PROTOCOL IN *SNAYUGATA AAGHATAJA SHOTHA* WITH SPECIAL REFERENCE TO ANKLE SPRAIN

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### ABSTRACT

Acute sprains from sports injuries frequently occur in the ankle joint. Acute ankle sprain is responsible for 10-30% of sports related injuries in young athletes. Ankle sprain symptoms include pain and swelling, either with or without deformity. Modern science developed treatment modalities for the ankle sprain are below knee cast, ankle brace and ankle strap. When an ankle sprain is not treated properly, it can lead to chronic problems like pain, instability in the joint and limited range of motion.

Acharya Sushruta suggests *Alepa* with *Sandhaniya Dravyas* for the management of *Snayugata Shotha*. When employed as a *Lepa*, these *Dravyas* possess the qualities of *Sandhaniya*, *Shodhahara*, and *Vedanashaman* action.

It is need of today era to develop Ayurvedic protocol for ankle sprain. Hence, this study is taken up to develop protocol according to Ayurved. Phase wise distribution of *Lepa*, *Patta Bhandhan* mentioned in this article.

### INTRODUCTION

Sports injuries are a broad category that includes everything from mild sprains to severe fractures. Ankle ligament injuries are among those that are commonly seen in daily practice. Ankle injuries commonly occur in clinical settings as a result of anterior talofibular ligament tears. This injury is followed by the injuries of posterior talofibular ligaments (PTFL). An ankle sprain is a common injury. Approximately 85% of all ankle sprains are Inversion-type, lateral ligament injuries, which are the most common type. Ankle sprains are most common in sports populations.

According to *Acharya Charak* ankle sprain closely correlated to *Snayugata Aaghataja Shotha*. *Shotha* cause by *Aagantuj Hetu* like *Prahar*, *Bhanjan*, *Pidan* by any type of external injury. *Shotha* cause by

*Aaghat* in ankle joint closely correlated to ankle sprain. [1]

Ankle braces, ankle supports, and other forms of immobilization are use in the modern methods of treating an ankle sprain and NSAIDS consumption for symptomatic relief. Apart from these characteristics, it does not possess any medicinal qualities that aid in the healing of ligamentous injuries. Thus, aim is develop Ayurvedic modified PRICE protocol for ankle sprain.

### AIM

To study the efficacy of Ayurved intervention in the management of *Snayugata Aaghataja Shotha* with special reference to ankle sprain on available clinical parameters.

### OBJECTIVE

To validate the efficacy of the Ayurveda protocol developed for ankle sprain in terms of improvement comparison to standard treatment protocol.

### MATERIAL AND METHODS

The study was an open-label, randomized, controlled clinical trial. Thirty patients who met the inclusion criteria were chosen from Shalya Tantra IPD and OPD departments. Two groups, Group A (N=15)

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and Group B (N=15), were formed out of them. Group B is the trial group; Group A is the control group. Before beginning the trial, the IEC approved it, all patients gave their informed written consent, and patients between the ages of 14 and 45 were included in the study. The course of treatment lasted for 21 days. Patients in both groups underwent follow-up every fifth day for 21 days, for a total of 4 sittings.

A detailed study was done regarding literature related to the *Snayugata Aaghataja Shotha*, sports injury, Ankle ligament complex injuries will be carried out to have clear idea about the subject. A total number of 30 patients encountered with the residual morbidity like pain, swelling, and tenderness after ankle injury despite any level of grading, were enrolled in this study. The observations are made on the various parameters such as pain, swelling, tenderness observation were made on 1<sup>st</sup> day, 5<sup>th</sup> day, 11<sup>th</sup> day, 21<sup>st</sup> day, as the final follow up.

### Diagnostic criteria

#### Inclusion Criteria

- Patients with typical history and clinical features pertaining to acute ankle sprain of grades I & II presented with in initial 72 hours of injury.
- Grade I: No laxity, minimal pain and mild swelling.
- Grade II: Mild to moderate laxity, soft tissue swelling, anterior drawer and talar tilt is slightly positive.
- Age 14-45 years
- Despite of any gender, caste and religion.
- Patients willing to undergo trial.

#### Exclusion Criteria

- Ankle Impingement
- Tarsal Tunnel Syndrome
- Sinus Tarsi Syndrome
- Cartilage or osteochondral injuries
- Peroneal Tendinopathy or subluxation
- Posterior Tibial Tendon Dysfunction
- Systemic disease - CVS, CKD
- Wound over ankle
- Ankle dislocation

#### Assessment Parameter

Time frame for assessment (Day of presentation, 5<sup>th</sup> day, 11<sup>th</sup> day, 21<sup>st</sup> day)

1. Pain as per visual analog scale (VAS).
2. Swelling (compared with UN-injured ankle taken circumferentially at same level).
3. Tenderness (using pressure algometer as per established scale).

### Study Protocol

Over all of study divided in 3 phase according to progress of healing

#### Standard group

##### Inflammatory Phase (0-5 days)

1. PRICE - Protocol: Protection, rest, ice compression and elevation.<sup>[2]</sup>
2. Ankle immobilization
3. Anti-inflammatory (serratiopeptidase with diclofenac potassium) twice daily with water.

##### Proliferative Phase (6-10 days)

1. Patient education regarding gradual increase in activity level, guided by symptoms.
2. Practise Foot and Ankle Functions focussing
  - Range of motion
  - Active stability
  - Motor coordination
3. Ankle brace
4. Anti-inflammatory (serratiopeptidase with diclofenac potassium) twice daily with water.

##### Early Remodelling (11 -21 days)

1. Patient education or do's & don'ts.
2. Ankle brace

##### Follow up for next 3 weeks (weekly interval)

#### Trial Group

Inflammatory Phase (0-5 days)

##### Modified PRICE

1. All the points under PRICE other than ice application.
2. Ice application will be replaced by *Nishadi Lepa* 2 times for 3 day.
3. Ankle immobilization
4. Anti-inflammatory (*Punarnavaadi Guggulu* 500mg twice daily with lukewarm water)

##### Proliferative Phase (6-10 days)

1. Patient education regarding gradual increase in activity level, guided by symptoms.
2. Practice foot and ankle functions focussing
  - Range of motion
  - Active stability
  - Motor coordination
3. Air cast ankle brace with *Gandha Taila Patta Bandhana*.
4. Anti-inflammatory (*Punarnavaadi Guggulu* 500mg twice daily with lukewarm water).

##### Early Remodeling (11 -21 days)

1. Patient education for do's & don'ts.
2. Ankle brace
3. *Gandha Taila* for internal usage.

## Treatment Procedure

### Application of *Nishadi Lepa*

1. Application of *Nishadi Lepa* twice daily to target the swelling of the injured ligament of ankle for 5 days with analgesic and anti-inflammatory effects.
2. Method of Preparation of *Nishadi Lepa*
  - The fine powder of *Haridra*, *Daruharidra*, *Shwet Chandan*, *Rakta Chandan*, *Durva*, *Punarnava*, *Usher*, *Padmak*, *Lodra*, *Rasanjan*, *Gairik* was taken in equal quantity.
  - The sufficient quantity of normal saline water was mixed to above said ingredients and mixed till it reached to semisolid state.
  - This is freshly prepared *Nishadi Lepa* and applied to affected area.

### Before treatment



### *Ganda Taila Pattabandhan*

*Gandha Taila* was taken on gauze piece and applied on affected part of ankle sprain for 12 hr and change that *Patta Bandhan* again for next 12 hr. This promotes sustained release of medicated oil on ankle sprain which gradually heals ligament tear.

### 1. *Poorvakarma*

Patient was positioned comfortably in the dressing room.

Affected area of ankle sprain was clean by normal saline with help of cotton swabs held in sponge holder.

### 2. *Pradhan karma*

Patient was made to sit on dressing table.

Application of Prepared *Nishadi Lepa* was done on affected area of ankle joint.

### 3. *Pashchath karma*

Plain sterile gauze was placed over the affected area and roller gauze was bandaged with moderate tension followed by application of crape bandage.

**Before Treatment**



**After treatment**



**OBSERVATIONS AND RESULT**

**Results**

The mean score for pain decreased from 1<sup>st</sup> day to last follow up day. There was highly significant results ( $p < 0.0001$ ) in pain in both group, the percentage of relief was more (92%) in Group B, the patients who underwent treatment with proposed Modified PRICE protocol as compared to Group A (87%), those who treated with Standard PRICE protocol.

Significant result was observed ( $P < 0.05$ ) in swelling, and the percentage of relief was more in Group B (84%) as compared to Group A (64%).

Though both the groups had shown highly significant ( $p < 0.0001$ ) results in tenderness, percentage of relief was more (73%) in Group B as compared to Group A (68%).

The patients who got treated with tested protocol (Modified PRICE protocol) had yielded better outcome when compared with standard PRICE protocol with better percentage of relief in pain, swelling, tenderness of the ankle sprain with highly significant p values in each parameter.

**Table 1: Showing effect of therapy in individual parameters- Pain, Swelling, Tenderness. (Friedman test)**

Variable	Group	Mean		Mean Diff.	% Relief	SD±	SE±	P	S
		BT	AT						
Pain	Gr. A	7.0	0.8667	6.133	87 %	0.8338	0.2153	<0.0001	HS
	Gr. B	6.333	0.4667	5.867	92%	0.7432	0.1919	<0.0001	HS
Swelling	Gr. A	1.667	0.6000	1.067	64%	0.4577	0.1182	0.0001	S
	Gr. B	1.267	0.200	1.067	84 %	0.4577	0.1182	0.0001	S
Tenderness	Gr. A	1.667	0.5333	1.133	68%	0.3519	0.01985	0.0001	S
	Gr. B	1.267	0.3333	0.9333	73%	0.2582	0.06667	0.0001	S

(HS: Highly Significant, S: Significant, NS: Non Significant)

Pain was assessed by taking means of pain of 15 patient in each group from day 1 to every day for four weeks were recorded, and their mean scores were subjected to One Way ANOVA test i.e., Friedman test.

**Pain**

- In Group A the mean Score before treatment was 7.000 which lower down to 0.8667 after treatment with SD± 0.8338 giving a relief of 87% and the value of P <0.0001 which statically highly significant.
- In Group B, the mean Score treatment was 6.333 which lower down 0.4667 after treatment with SD ± 0.7432 giving relief of 92% and P value <0.0001 which statistically highly significant.

**Swelling**

- In Group A the mean Score before treatment was 1.667 which lower down to 0.6000 after treatment with SD ± 0.4577 giving a relief of 64% and the value of P <0.0001 which statically Significant.
- In Group B, the mean Score treatment was 1.267 which lower down 0.200 after treatment with SD ± 0.4577 giving relief of 84% and P value <0.0001 which statistically Significant.

**Tenderness**

- In Group A the mean Score before treatment was 1.667 which lower down to 0.5333 after treatment with SD ± 0.3519 giving a relief of 68% and the value of P <0.0001 which statically Significant.
- In Group B, the mean Score treatment was 1.267 which lower down 0.3333 after treatment with SD ± 0.2582 giving relief of 73% and P value <0.0001 which statistically Significant.

**Inter Group Comparison**

Assessment parameter	Mean rank diff.	P value	Mann Whitney Test (U)	Results
Pain	4.54	0.1677	78.50	NS
Swelling	6.00	0.0604	67.50	NS
Tenderness	3	0.4621	90	NS

The disease, ankle sprain describe in modern class can be correlated with the *Aghataj Shotha* of ankle region, on the basis of similar clinical features. External as well as internal treatment is important in the management of ankle sprain.

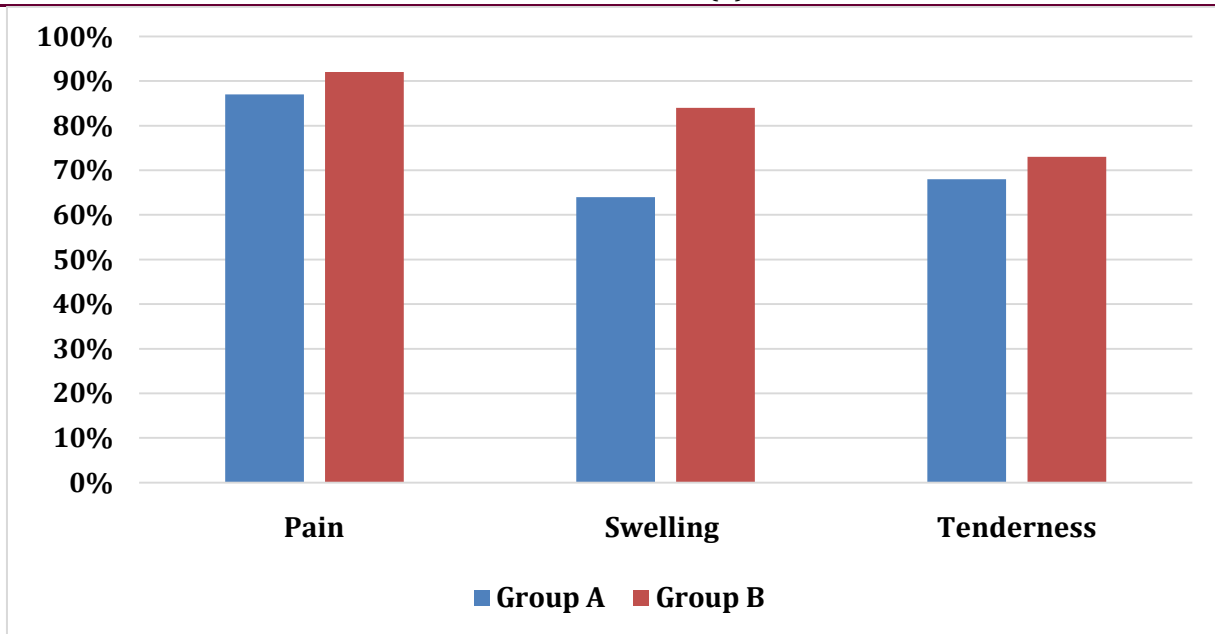
**Inter Group Comparison of Group A and Group B for Pain, Swelling, Tenderness.**

Variable	Group	Mean AT	SD±	SE±	P	S
Swelling	B	0.4667	0.7432	0.1919	0.0001	NS
	A	0.6000	0.4577	0.1182		
Tenderness	B	0.200	0.4577	0.1182	0.0001	NS
	A	0.5333	0.3519	0.0198		
	B	0.333	0.2582	0.06667		

- **Pain:** The value of P < 0.0001 is statistically **non-Significant**, which shows that there is no statistical difference in the efficacy of the both treatments on pain.
- **Swelling:** The value of P is equal to 0.0001, is statistically **non-Significant**, which shows that there is no statistical difference in the efficacy of the both treatments on swelling.
- **Tenderness:** The value of P is equal to 0.0001, is statistically **non-Significant**, which shows that there is no statistical difference in the efficacy of the both treatments on tenderness.

**Percentage difference in individual variables of group A and group B after treatment**

Sr.No.	Parameter	Group A	Group B
1.	Pain	87%	92%
2.	Swelling	64%	84%
3.	Tenderness	68%	73%



### Secondary Outcomes

To test the efficacy of the proposed protocol developed for Ankle Sprain by incorporating the Ayurveda in comparison to standard treatment protocol.

According to above observation, statistically that both group have similar relieving effect of pain, swelling, tenderness. Thus give evidence to develop Ayurved protocol for ankle sprain.

### Probable Mode of Action of Modified PRICE Protocol

In standard group the management was planned as per the standard PRICE protocol for ankle sprain. In the trial group, there are modified PRICE protocol has been proposed incorporating the *Nishadi Lepa*, *Gandha Taila* and *Punarnavadhi Guggulu*. In acute ankle sprain we observe that *Nishadi Lepa* is acting to reduce acute swelling and pain for initial 5 day [3]. After application of *lepa* for 5 days, swelling reduced adequately. After 5 days *Gandha Taila Patta Bhandhan* applied to affected ankle joint. *Gandha Taila Patta Bhandhan* helps in healing of ligament tear.[4] Also *Patta Bhandhan* immobilized the injured ankle sprain that also helps in healing of ligament tear. *Punarnavadhi Guggulu* has an anti-inflammatory effect thus it reduces *Shotha*. [5] When we compared Modified developed PRICE protocol with standard protocol, we observe that both protocol have nearly similar effect on ankle sprain treatment.

As the tested protocol has exhibited nearly similar effect in the ankle sprain treatment hence establishing the efficacy of the tested protocol.

### CONCLUSION

The following points can be made on conclusion based upon the total result work done during the study.

- The disease, ankle sprain describe in modern class can be correlated with the *Aaghataj Shotha* of ankle region, on the basis of similar clinical features.
- Study shows both groups exhibiting the similar results in the assessment parameter. Thus, the alternate hypothesis i.e., "There is difference between trial group and control group in the management of *Snayugata aaghataja shoth* w.s.r to ankle sprain" is rejected and null hypothesis i.e., "There is no difference between trial group and control group in the management of *Snayugata aaghataja shoth* w.s.r to ankle sprain" is accepted.
- Tested protocol (proposed Ayurveda protocol) can replace the standard group for effective management of ankle sprain.
- Most of the sports injuries involving the soft tissue in the joints encountered on today, era can be closely related to various condition of *Sandhimukta* and *Snayugata Aaghataj Shotha* described by *Acarya Susruta* under the heading of *Bhagna* and *Snayugata Aaghataj Shotha*.
- *Nishadi Lepa* is the appropriate drug for the management of *Snayugata Aaghataj Shotha* which should be further studied in the large number of samples.
- The *Gandha Taila* is the appropriate drug for the management of *Snayugata Aaghataj Shotha*.
- The overall effect of protocol is found effective and should be studied in large number of samples.

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