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Clinical trial to evaluate the efficacy of *Sandhaniya* Cast in Ankle Sprain

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ABSTRACT

Ankle is the most common site for acute musculoskeletal injuries and sprains. Acute ankle trauma is responsible for 10-30% of sports related injuries in young athletes. Ankle sprain is characterized by pain, swelling with or without deformity. According to the Modern science the treatment modalities adopted for the ankle sprain are ankle brace, below knee cast and ankle strap. Inadequate treatment of ankle sprain can lead to chronic problems such as decreased range of motion, pain and joint instability. *Acharya Sushruta* advocates *Alepa* with *Asthisandhaniya Dravyas* for the management of *Bhagna*. These *dravyas* when used in the form of *Lepa* have the properties of *Sandhaniya*, *Shophahara* and *Vedanasthapaka* action. It is a need of hour to bring up new innovative, readily available, patient friendly and time saving techniques which possess the same effect. Hence this study is taken up to bring the *Manjistadi Lepa* in the modified form as *Sandhaniya* cast. Such kind of medicated casts weren't in use till date which makes it unique. This would not only help in immobilization like any other ankle brace or ankle binder, but also reduces localized edema and pain due to its *Vedanasthapaka* and *Shophahara* properties and also accelerates the healing.

Key words: *Sandhaniya Cast, Ankle Sprain, Ankle Brace, Manjistadi Lepa*

INTRODUCTION

Ankle sprains are the most common of all sports related injuries, accounting for over 25% of cases. This is the most common musculoskeletal injury with an incidence of 1/10,000/day.[1] In 85 percent of cases, it is due to inversion of supinated plantar flexed foot. In more than 75% of cases, it is the lateral ligament complex that is injured, in particular the anterior talofibular and calcaneofibular ligaments. Medial ligament injuries are usually associated with a fracture or joint injury. Lateral ankle sprain is the most common soft tissue limb injury and < 15 percent actually show a significant fracture. Conventional method of treating an ankle sprain includes various immobilization methods like ankle brace, ankle support etc. Along with regular intake of NSAIDS for symptomatic relief.[2]

Other than these features, it doesn't hold any medicinal property to promote healing of ligamentous injury which is seen in ankle sprain. Thus, *Manjistadi Lepa* explained by *Acharya Sushruta* in *Bhagna Chikitsa* is modified as *Sandhaniya* cast is an attempt to bring a holistic evidence-based approach for the management of ankle sprain.[3] Such kind of medicated casts weren't

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in use till date which makes it unique. This would not only help in immobilization like any other ankle brace or ankle binder, but also reduces localized edema and pain due to its *Vedanasthapaka* and *Shophahara* properties and also accelerates healing.

Aim

To evaluate the efficacy of *Sandhaniya* cast in the management of ankle sprain.

Objectives

1. To prepare and standardize *Sandhaniya cast*.
2. To evaluate the effect of Ankle Brace.
3. To evaluate the efficacy of *Sandhaniya* cast in ankle sprain
4. To compare the effect of *Sandhaniya* cast with Ankle Brace in the management of ankle sprain.

Materials and Methods

The study design was open label, randomized controlled clinical study, in this study 30 patients who fulfilled the inclusion criteria were selected from OPD, IPD department of Shalya Tantra. They were divided into two groups Group A (N=15) and Group B (N=15). Group A being the control group and Group B being the trial group. IEC approval was taken before starting the trail, informed written consent of all patients was taken before the operative procedure, and for patients below 21 years of age consent was obtained from parents or guardians. Duration of treatment was till 21 days. Follow up of the patients was carried out on every 3rd day for 21 days in both the groups with total of 6 sittings.

Preparation of *Sandhaniya* cast

Sandhaniya cast was prepared under 4 stages:

1. Preparation of *Manjistadi Lepa.*
2. Application of *Manjistadi Lepa* over standard cora cloth.
3. Drying of medicated cora cloth.
4. Packing of *Sandhaniya* cast.

Preparation of *Sandhaniya Lepa*

Equipments used - vessels, cloth, stove.

Ingredients

1. *Manjista Churna - 10g*
2. *Yastimadhu Churna - 10g*
3. *Raktachandana Churna - 10g*
4. *Shali Churna - 10g*
5. *Shatadhouta Grtha - 10ml*
6. *Jala - 120ml*

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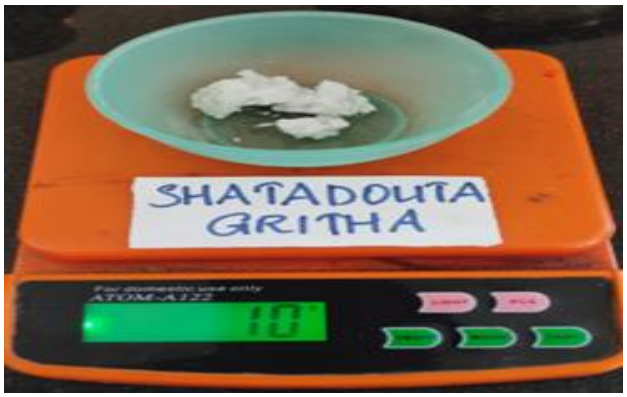

Procedure

The previously mentioned drugs were taken in quantity of 10g each fine powder from a GMP certified pharmaceutical company.

The *Lepa* was prepared by adding 120ml water and heated, till it attains a paste like consistency of total 150grams.

Application of *Manjistadi Lepa* over standard cora cloth

Now this *Lepa* was applied to Cora Cloth having dimensions of 150cm long X 8cm width,

Uniformly with equal thickness across the cloth.

Drying of medicated cora cloth

The cora cloth was then carefully placed in hot air oven at 40° Celsius for a duration of 2 hours.

Packing of *Sandhaniya* cast

The dried cast was then removed from hot air oven after 2 hours and preserved in air tight container and were ready to use in this trial.

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Intervention (Group-B)

Sandhaniya cast dipped in warm water (100˚F) for 15 seconds just before to the application and its applied around the affected ankle in figure of 8 method of bandaging.

Control Group (Group A)

Procedure - Affected ankle is examined and ankle brace was applied

Diagnostic criteria

All the classical features of ankle sprain including[4]

- Pain
- Swelling
- Difficulty in walking
- X-ray of the affected Ankle joint AP & Lateral view (to rule out fracture).

Inclusion criteria

- **Age -** between 21 - 60yrs
- **Sex -** both male and female.
- Patients with Grade 1 and grade 2 ankle sprains.

Grade 1 Ankle sprain

The symptoms tend to be limited to pain and swelling, most patients can walk without crutches, but may not able to jog or jump.[5]

Grade 2 Ankle sprain

There is usually more significant swelling and bruising caused by bleeding under the skin. Patients usually have pain while walking but can take few steps.[5]

Exclusion criteria

- Subjects with fracture and dislocation of ankle joint.
- Subjects with Grade- 3 Ankle sprain. (Grade 3 Ankle sprain: Ankle is usually quite painful and walking can be difficult, patients may complain of instability or a giving-away sensation in ankle joint)[5]

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- Subjects with previous history of ligament or bony reconstructive surgery to the ankle & foot.
- Subjects presenting with wound over ankle along with sprain will be excluded.

Criteria of assessment (subjective & objective)

The patients were assessed based on subjective and objective parameters.

Subjective parameter - Karlsson scoring scale[6]

Objective parameter

- Range of motion for Plantar Flexion.
- Range of motion for Dorsi Flexion.
- Range of movement for Inversion.
- Range of movement for Eversion.
- Ankle girth

Observations and Results

Observation during preparation of *Sandhaniya* cast

- *Shali Churna* was difficult to mix in *Lepa* forming lumps.
- Red color of the *Lepa* and pleasant odour of the preparation were appreciated.
- *Shatadhouta Grtha* gives *Lepa* a smoother consistency.
- Application of *Lepa* over the cora cloth was difficult to spread uniformly all across.
- The outer borders of cora cloth if not stitched leads to loose threads all across the bandage.
- Wet cast immediately after the application of *Lepa* needs utmost care to avoid spillage of *Lepa* and sticking to itself
- Placing the wet bandage in hot air over was found difficult.
- No powdering was noted after the cast was dried.
- Packing the cast without proper drying leads to formation of fungus due to left over moisture.
- Air tight containers had served better in packaging compared to the normal packing.
- Greater than 2 months of storage led to powdering of the *Lepa* from cast and change in odour.

Observations during intervention

Group - A

- Ankle brace was easy to apply.
- It was non-irritant.
- Facilitated easy and painless removal.

Group - B

- Application of *Sandhaniya* cast was easy.
- Negligible amount of wastage was noted when the dried bandage was dipped before application.
- Cast should be left immobilized for at least 3 hours for setting period.
- Cast was easy to remove without much manipulation to the ankle.
- *Sandhaniya* cast caused mild itching and irritation after drying.
- Colour of *Lepa* i.e., red colour was left over ankle after removal of cast.

Results

Table 1: Between the group comparison (BT & AT) for Anterior drawer test.

Change in Anterior drawer test between BT and AT	Group A		Group B		Total		Mann Whitney U test	
	N	%	N	%	N	%	z	p
No change	2	13.3	0	0	2	6.7	1.439	0.150
Improved	13	86.7	15	100	28	93.3		
Total	15	100	15	100	30	100		

Table 2: Between the group comparison (BT & AT) for Inversion talar tilt.

Change in Inversion talar tilt test between BT and AT	Group A		Group B		Total		Mann Whitney U test	
	N	%	N	%	N	%	z	p
No change	0	0	0	0	0	0		

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Improved	15	100	15	100	30	100	0.000	1.000
Total	15	100	15	100	30	100		

Table 3: Between the group comparison (BT & AT) for Karlsson scoring scale

Karlsson scoring scale		Group A		Group B		Total		Mann Whitney U test	
		N	%	N	%	N	%	z	p
BT	Poor	15	100	15	100	30	100	0.000	1.000
AT	Excellent	5	33.3	10	66.7	15	50	1.795	0.073
	Good	10	66.7	5	33.3	15	50		

Table 4: Between the group comparison (BT & AT) for Ankle girth.

Ankle girth (cm)	Group A		Group B		Unpaired t test	
	Mean Rank	SD	Mean Rank	SD	t	p
BT	25.5	1.4	26.3	3.2	0.963	0.344
AT	23.9	1.3	24.4	3.2	0.643	0.526
Change in Ankle girth	1.6	0.6	1.9	0.7	1.245	0.224

There was a significant difference before and after the treatment between the groups with high clinical efficacy seen in Group B compared to Group A in respect to subjective and objective parameters. Pain and swelling reduced in Group B by 2nd sitting whereas in Group A it was delayed upto 4th sitting.

DISCUSSION

Rakta Prasadaka, Vatapitta Shamaka, Twak prasadaka, Shotahara, Shoolahara & *Sandhaneeya* properties of *Sandhaniya* cast is assumed to target acute nature and associated attributes like pain, swelling, reduced range of movements of ankle joint due to ligamentous injury, localized oedema and soft tissue injury of ankle.

The standardized form of *Sandhaniya* cast was sufficient enough to produce the therapeutic effect. Furthermore, the formulation in the form of *Sandhaniya* cast is apt for the ankle injury with grade-1 to grade-2 ankle sprains, providing adequate immobilization amplifying healing of injured ligaments. Along with Glycyrretic acid of *Yastimadhu*, extract of *Manjista* and decoction of *Raktachandana* proved to have anti-inflammatory action reducing the localised oedema, pain and discomfort during ankle sprain.

LIMITATIONS

For Assessment of subjective & objective criteria for total 6 sittings across 21 days, subjects faced difficulty to visit to OPD frequently with ankle sprain.

Subjects faced difficulty to avoid weight bearing over affected ankle joint during the course of treatment as ankle is important weight bearing joint.

Control Group

Before the treatment

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Ankle brace

After the treatment

Trail Group

Before the treatment

***Sandhaniya* cast**

After the treatment

CONCLUSION

Sandhaniya cast not just seemed to exhibit the qualities of an ideal immobilization method, but also appeared to manifest its therapeutic effects of the formulation impregnated in it in a standardized dose. *Sandhaniya* cast could be a better alternative for ankle brace in the management of ankle sprain.

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