



## Research Article

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### EVALUATION OF COMBINED EFFECT OF ARJUNA KSHEERAPAKA AND POSTERIOR SLAB WITH STANDARD OF CARE IN RADIUS FRACTURE: A COMPARATIVE CLINICAL TRIAL

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#### ABSTRACT

**Introduction:** Bone healing is a complex process of tissue recapitulation which requires various anatomical and biomechanical processes in a well-orchestrated manner. Radius fractures account for 25% of fractures in the paediatric population and 18% in the elderly. Its treatment ranges from closed reduction and immobilisation to complex operative treatments. Ancient ayurvedic literature and various pharmacological studies deciphered the use of *Terminalia arjuna* in the bone healing process. **Materials and Methods:** The study aims to analyse the bone healing effect of Arjuna kṣīrapāka along with its effectiveness in reducing pain, swelling, tenderness, deformity and loss of function in a sample of 30 patients. Patients were recruited into two groups, with 15 patients in each group. Assessments were done before treatment, on the 30<sup>th</sup> day and after treatment. **Result and Discussion:** The clinical assessments after treatment showed that 80% got a complete cure in the group treated with Arjuna kṣīrapāka, while the standard treatment group only had a 53.3% cure rate. The combination of kṣīra with Arjuna increases the bioavailability of active principles of Arjuna. Casein helps for easy delivery of active principles of *Terminalia arjuna*. Active principles of *Terminalia arjuna*, like tannins, help with bone tissue regeneration. Hence *Terminalia arjuna* is excellent for its osteo-potential activity, especially as milk preparation. **Conclusion:** The combined use of Arjuna kṣīrapāka and the POP posterior slab was more significant than the standard care alone in the healing of radius fracture in callus formation and mobility between fragments.

**Keywords:** Bhagnā, Arjuna Kṣīrapāka, Fracture healing, Fracture, Ayurveda

#### INTRODUCTION

Bone healing is a complex and sequential process aiming to restore the exact anatomy of the bone. Injury to bone remains a constant counterpart to human existence, and due to bone healing, we can cope with this situation. Radius fractures are the most common orthopaedic injury, which accounts for 18% of all fractures in adults. It has a bimodal age distribution. The injury mechanism is high energy velocity trauma in a younger person and low energy mechanisms like FOOSH (Fall on an outstretched hand) in the elderly.<sup>1</sup> Between the age groups of 19-49 years, distal radius fractures are more common in men than in women, which may be due to their involvement in sports activities and motor vehicle accidents.<sup>2</sup> Depending on the fracture type and fracture fixation and immobilisation method, fracture healing is of two types – Healing without callus formation (Primary) and Healing by callus formation (secondary). Primary fracture healing is a direct attempt of bone to restore its continuity without forming a callus; it is seen in rigid internal fixation of fractures and unicortical fractures. The most common secondary fracture healing method is the absence of rigid fixation, such as cast immobilisation.<sup>3</sup> Other than this, the age of the patient, type of bone, fracture pattern, immobilisation etc., also affects the fracture healing. This biological process sometimes fails and is complicated by impaired healing, like the development of non-union or delayed union, and it negatively affects the patient's quality of life and may require a second surgery to stabilise the fracture and normalise bone functions. In such conditions, early healing is needed to prevent further complications affecting the patient's quality of life.

Thus arise the need for an advanced study that promotes the early healing of the fracture. In recent years, ethnobotanical studies have been essential and received much attention as they are the repository of original knowledge about medicinal plants. Medicinal plants are well-tested for efficacy and provide definite physiological action on the human body. Among these, one of the medicinal plants indigenous to India is *Terminalia arjuna*. Chakrapani Dutta mentions the importance of arjuna Kṣīrapāka in Bhagnā in his compendium Chakradatta, Bhagnā chikitsa adhikara. Recent *in vitro* and *in vivo* research shows that *Terminalia arjuna* has anti-inflammatory and analgesic properties and its capability for early healing by calcification and bone regeneration.<sup>5,6</sup> The present study was focused on evaluating the effect of arjuna Kṣīrapāka along with POP posterior slab in the healing of radius fracture and in reducing pain, swelling, tenderness, deformity and loss of function.

#### MATERIALS AND METHODS

The study was designed as an open-labelled double-armed comparative clinical trial (registered with Clinical Trial Registry of India – CTRI/2019/12/022476) in which 34 patients were examined, and an X-ray was taken. Of these, 30 patients satisfying the inclusion criteria were selected. We have included the age group of 20-40 years, Simple radius fracture diagnosed by X-Ray and Radius fracture with a history of trauma within 72 hours. Other diagnosed osteogenic pathologies like bone cysts, osteomalacia, bone tumour, osteomyelitis, rickets etc., compound, comminuted fractures and fractures of both radius and ulna were excluded. Patients who are willing to undergo trial are only selected. These patients were recruited into two groups by

simple random sampling, with 15 patients in each group. Prior informed consent was obtained from the patient for the study. During treatment, if any other medication is required for managing the associated complaints of fracture, the patient will be withdrawn from the study. Group A patients received POP posterior slab with Arjuna kṣīrapāka (96 ml) internally once daily for 45 days, and group B received POP posterior slab. Rebandaging was done on the 15<sup>th</sup> day. The assessment was done on the 0<sup>th</sup> day, 30<sup>th</sup> day and 45<sup>th</sup> day. The additional effect of Arjuna kṣīrapāka in Group A with POP posterior slab has been compared with the effect of POP posterior slab alone in Group B.

The assessment criteria include Pain, Swelling<sup>7</sup> (Measuring circumference in cm and comparing with normal limb), tenderness,<sup>8</sup> deformities. Test of clinical union<sup>9</sup> (Absence of mobility between fragments and absence of pain on angulation stress) and radiological criteria of union<sup>10</sup> (Visible callus on X-ray and continuity of bone trabeculae) was assessed. In addition, we have used RUST (Radiological union score for tibia) and RUSH (Radiological union score for hip) score, novel fracture assessment tools developed for standardisation of radiographic assessment of tibia and hip, which we have used in radius fractures.<sup>11</sup> This score assesses radiographic signs of fracture

healing. It has the potential to serve as a reliable scoring system to help quantify the recovery. The clinical and radiological assessments before treatment, on the 30<sup>th</sup> day and the 45<sup>th</sup> day, were statistically analysed by Wilcoxon signed rank test, which is used to assess the efficacy of treatment within groups, Mann Whitney u test to evaluate the effectiveness of treatment in between groups and efficacy of treatment in RUST and RUSH score between groups was calculated using paired t-test. The level of significance was noted and interpreted accordingly.

**RESULT**

**Effect of treatment on clinical signs and symptom**

While considering the effect of treatment on pain, swelling, tenderness, loss of function and deformity, both the groups were found to be equally significant with a P value <0.05. (Table 1)

Mann-Whitney U Test statistically analysed the treatment effect between Group A and Group B. It was analysed that pain, swelling, deformity, tenderness and Loss of function were equally reduced in both groups. (Table 2)

**Table 1: Effect of treatment on clinical signs and symptoms within the group**

Chief Complaint	Groups		Mean	Std. Deviation		Z value	p-value	Remark
Pain	Group A	BT	2.267	0.704				
		30 <sup>th</sup> Day	0.867	0.640	BT - 30 <sup>th</sup> Day	-3.520*	<0.001	HS
		AT	0.133	0.352	BT - AT	-3.464*	0.001	S
	Group B	BT	2.067	0.799				
		30 <sup>th</sup> Day	1.067	0.799	BT - 30 <sup>th</sup> Day	-3.873*	<0.001	HS
		AT	0.333	0.488	BT - AT	-3.578*	<0.001	HS
Swelling	Group A	BT	1.533	0.640				
		30 <sup>th</sup> Day	0.333	0.488	BT - 30 <sup>th</sup> Day	-3.448*	0.001	S
		AT	0.067	0.258	BT - AT	-3.508*	<0.001	HS
	Group B	BT	1.533	0.915				
		30 <sup>th</sup> Day	0.600	0.507	BT - 30 <sup>th</sup> Day	-3.276*	0.001	S
		AT	0.267	0.458	BT - AT	-3.272*	0.001	S
Deformity	Group A	BT	1.267	0.704				
		30 <sup>th</sup> Day	0.467	0.516	BT - 30 <sup>th</sup> Day	-3.464*	0.001	S
		AT	0.133	0.352	BT - AT	-3.153*	0.002	S
	Group B	BT	1.067	0.884				
		30 <sup>th</sup> Day	0.333	0.488	BT - 30 <sup>th</sup> Day	-3.051*	0.002	S
		AT	0.067	0.258	BT - AT	-2.879*	0.004	S
Tenderness	Group A	BT	1.733	0.704				
		30 <sup>th</sup> Day	0.667	0.617	BT - 30 <sup>th</sup> Day	-3.557*	<0.001	HS
		AT	0.133	0.352	BT - AT	-3.384*	0.001	S
	Group B	BT	1.533	0.516				
		30 <sup>th</sup> Day	0.467	0.516	BT - 30 <sup>th</sup> Day	-3.771*	<0.001	HS
		AT	0.133	0.352	BT - AT	-3.520*	<0.001	HS
Loss of function	Group A	BT	1.467	0.640				
		30 <sup>th</sup> Day	0.733	0.594	BT - 30 <sup>th</sup> Day	-3.051*	0.002	S
		AT	0.200	0.414	BT - AT	-3.416*	0.001	S
	Group B	BT	1.400	0.507				
		30 <sup>th</sup> Day	0.600	0.632	BT - 30 <sup>th</sup> Day	-3.464*	0.001	S
		AT	0.200	0.414	BT - AT	-3.626*	<0.001	HS

Wilcoxon Signed Ranks Test, \* Significant at 0.05 level. BT: Before Treatment, AT: After Treatment

**Table 2: Effect of treatment on clinical signs and symptoms between groups**

Chief Complaints	Group A			Group B			Z value	p-value
	Mean	Std. Deviation	Mean Rank	Mean	Std. Deviation	Mean Rank		
Pain	0.733	0.594	15.367	0.733	0.458	15.633	-0.101	0.920
Swelling	0.267	0.458	15.000	0.333	0.488	16.000	-0.392	0.695
Deformity	0.333	0.488	16.000	0.267	0.458	15.000	-0.392	0.695
Tenderness	0.533	0.516	17.000	0.333	0.488	14.000	-1.087	0.277
Loss of function	0.533	0.516	16.500	0.400	0.507	14.500	-0.720	0.472

Mann-Whitney U Test, \*Significant at 0.05 level

**Table 3: Effect of treatment on a test of union within groups**

Chief Complaints	Groups		Mean	Std. Deviation		Z value	p-value	Remark
Callus formation	Group A	BT	0.000	0.000				
		30 <sup>th</sup> Day	0.800	0.414	BT - 30 <sup>th</sup> Day	-3.464*	0.001	S
		AT	1.733	0.458	BT - AT	-3.578*	<0.001	HS
	Group B	BT	0.000	0.000				
		30 <sup>th</sup> Day	0.267	0.458	BT - 30 <sup>th</sup> Day	-2.000*	0.046	S
		AT	0.800	0.775	BT - AT	-2.762*	0.006	S
Bone trabeculi	Group A	BT	0.000	0.000				
		30 <sup>th</sup> Day	0.067	0.258	BT - 30 <sup>th</sup> Day	-1.000	0.317	NS
		AT	0.733	0.458	BT - AT	-3.317*	0.001	S
	Group B	BT	0.000	0.000				
		30 <sup>th</sup> Day	0.000	0.000	BT - 30 <sup>th</sup> Day	0.000	1.000	NS
		AT	0.400	0.507	BT - AT	-2.449*	0.014	S
Angulation stress	Group A	BT	1.000	0.000				
		30 <sup>th</sup> Day	0.667	0.488	BT - 30 <sup>th</sup> Day	-2.236*	0.025	S
		AT	0.067	0.258	BT - AT	-3.742*	<0.001	HS
	Group B	BT	1.000	0.000				
		30 <sup>th</sup> Day	0.800	0.414	BT - 30 <sup>th</sup> Day	-1.732	0.083	NS
		AT	0.133	0.352	BT - AT	-3.606*	<0.001	HS
Mobility between fragments	Group A	BT	0.867	0.352				
		30 <sup>th</sup> Day	0.133	0.352	BT - 30 <sup>th</sup> Day	-3.317*	0.001	S
		AT	0.000	0.000	BT - AT	-3.606*	<0.001	HS
	Group B	BT	0.667	0.488				
		30 <sup>th</sup> Day	0.533	0.516	BT - 30 <sup>th</sup> Day	-1.414	0.157	NS
		AT	0.333	0.488	BT - AT	-2.236*	0.025	S

Wilcoxon Signed Ranks Test, \* Significant at 0.05 level. BT: Before Treatment, AT: After Treatment

**Table 4: Effect of treatment on the Test of union**

Test of Union	Group A			Group B			Z value	p-value
	Mean	Std. Deviation	Mean Rank	Mean	Std. Deviation	Mean Rank		
Callus formation	-1.733	0.458	10.700	-0.800	0.775	20.300	-3.231*	0.001
Bone trabeculae	-0.733	0.458	13.000	-0.400	0.507	18.000	-1.811	0.070
Angulation stress	0.933	0.258	16.000	0.867	0.352	15.000	-0.598	0.550
Mobility between fragments	0.867	0.352	19.500	0.333	0.488	11.500	-2.931*	0.003

Mann-Whitney U Test, \*Significant at 0.05 level

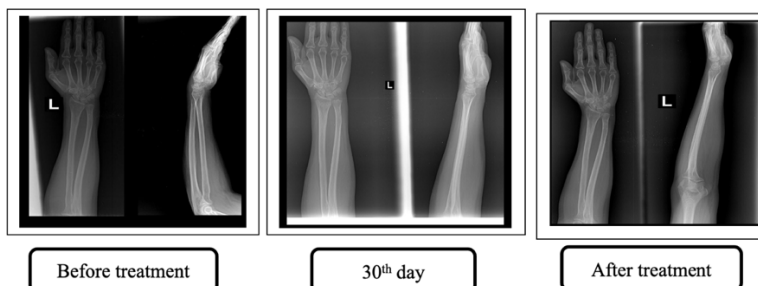
**Table 5: Effect of treatment in RUST and RUSH score**

	Group A		Group B		Mean Difference	t value	p-value
	Mean	Std. Deviation	Mean	Std. Deviation			
Rust Score	-5.400	1.724	-5.267	1.438	-0.133	-0.230	0.820
Rush Score	-15.267	2.738	-13.733	3.305	-1.533	-1.384	0.177

Independent Samples t Test, \*Significant at 0.05 level

**Table 6: Percentage of overall Relief**

Overall Relief		Group A		Group B	
		Frequency	Percent	Frequency	Percent
Cured	81 - 100%	12	80.0	8	53.3
Maximum improvement	61 - 80%	2	13.3	3	20.0
Moderate improvement	41 - 60%	1	6.7	3	20.0
Mild improvement	21 - 40%	0	0.0	1	6.7
No improvement	0 - 20%	0	0.0	0	0.0
Total		15	100.0	15	100.0



### Effect of treatment on Test of union

On assessing the effect of treatment on callus formation, continuity of bone trabeculae, angulation stress and mobility between fragments within groups, both the groups showed equal significance with a P value <0.05. (Table 3)

Mann-Whitney U Test statistically analysed the treatment effect between Group A and Group B. In Callus formation and Mobility between fragments, there is a significant difference between group A and Group B. It was analysed that; Bone trabeculae and Angulation stress were equally reduced in both groups. (Table 4)

### Effect of treatment on RUST and RUSH score

Independent Samples T Test statistically analysed the treatment effect between Group A and Group B. It was analysed that both groups' Rust and Rush scores were equally reduced. (Table 5)

### Percentage of Overall Relief

Clinical assessment after treatment (45 days) revealed that 80% of group A got completely cured, and 53.3% of group B got a complete cure. 13.3% in group A got maximum improvement, while 20% in group B got maximum improvement. Moderate improvement was there for 6.7% in group A and 20% in group B. In group B; mild improvement was there for 6.7%. Compared to group B, group A showed significant changes in callus formation and mobility between fragments with a p-value <0.001. In the case of pain, swelling, tenderness, loss of function, deformity, and angulation stress, it was equally reduced in both groups. (Table 6)

### DISCUSSION

Arjuna has kaṣāya and tikta rasa, and when given in the form of kṣīrapāka, madhura rasa is also incorporated into this, and these rasas predominantly have prithvi, agni, vāyu mahābhūta which helps in the formation of asthi dhātu. This tikta rasa has the ability to reach up to asthi dhātu and produces kharatwa, and ksheera helps to neutralise the excessive effect of tikta rasa and which is Vāta shamaka and does asthi poṣaṇa.<sup>12</sup> When Arjuna is given as kṣīrapāka, the gunas of kṣīra – madhura rasa, madhura vipāka, śīta vīrya, balya and jeevaniya properties also help in enhancing the process of healing. Milk contains minerals and vitamins and is a rich source of calcium, phosphorous, magnesium etc. lactose in milk aids optimum absorption of calcium, with the addition of a drug with an optimum amount of phytoconstituents increasing its therapeutic action.<sup>13</sup> Combination of kṣīra with arjuna increases the bioavailability of arjuna's active principles due to casein's presence. Casein enhances the bioavailability of active components through digestive alteration and oxidation by entrapping in casein molecules, increasing their solubility. When this casein binds with calcium phosphate, it forms a promising agent for controlled drug delivery.<sup>14</sup> Active principles of *Terminalia arjuna*, like tannins, saponins and triterpenoids, also help bone tissue regeneration. *Terminalia arjuna*'s anti-inflammatory and analgesic activity may be due to the inhibition of prostaglandin synthesis.<sup>15</sup> Quercetin, a phytoestrogen present in the drug, enhances callus formation by increasing the activity of alkaline phosphate activity and thus enhances bone mineralisation activity.<sup>16</sup>

### CONCLUSION

Though *Terminalia arjuna* is known for its potent cardio stimulant and cardiogenic activity, the asthi sandhāniya karma of Arjuna kṣīrapāka is significant. The combination of kṣīra with arjuna increases the bioavailability of active principles of arjuna,

and kṣīra would have synergised the function of asthi dhātu poṣaṇa. Active principles of *Terminalia arjuna*, like tannins, saponins and triterpenoids, also help bone tissue regeneration. Hence *Terminalia arjuna* is astounding for its osteo-potential activity, especially in milk preparation. The pre-clinical studies done to evaluate the healing effect of Arjuna kṣīrapāka had supported in a baseline manner. The combined use of Arjuna kṣīrapāka and the POP posterior slab was more significant than the standard care alone in the healing of radius fracture in callus formation and mobility between fragments.

**Patient Perspective:** Able to do daily activities much more ease than before without pain.

**Limitations of Study:** A well-developed protocol can be studied in a larger population to assess its efficacy.

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