



A CLINICAL STUDY ON EFFECT OF PEETVARATIKA CHURNA IN THE CALLUS FORMATION AND EARLY MOBILIZATION IN THE MANAGEMENT OF ASTHIBHAGNA WITH SPECIAL REFERENCE TO COLLES' FRACTURE

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ABSTRACT

Colles's fracture is the commonest fracture in elderly people and is predominantly common in women after the age of 45 because of post-menopausal osteoporosis particularly affecting the cancellous bone present in the lower end of radius. Standard treatment for the colle's fracture is post reduction below elbow immobilization of the wrist joint in plaster of Paris cast for six weeks. This immobilization leads to a common complication i.e. post-traumatic stiffness affecting mainly the wrist along with elbow and shoulder joint of the affected side accompanied by other immobilization induced complications. So in concern to this a clinical study was planned to evaluate the effect of early discontinuation the plaster of Paris cast after 4 week (instead of 6 weeks) along with the Varatika Bhasma in Colles' fracture Type I / Type II (Universal Classification Fracture Colle's). For this study 30 patients were selected and randomly divided in 2 groups i.e. Group A and B. Group A patients were treated with Varatika Bhasma orally along with post reduction immobilization in below elbow Plaster of Paris colle's cast for 4 weeks. Group B patients were treated with post reduction immobilization in below elbow Plaster of Paris Colle's cast for 6 weeks and a Placebo orally. After completion of the clinical study results were analyzed on various objective parameters and it was observed that Varatika Bhasma possesses potential of promoting fracture healing by enhancing the rate of callus formation. It was also observed that after the completion of treatment patients in group A showed regaining of early and better movements in the affected wrist joint along with elbow and shoulder joint of affected side.

Keywords: Varatika Bhasma, Asthibhagna, Colles' fracture.

INTRODUCTION

Colles' fracture is a distal radius fracture occurring within 2.5 cm of the wrist and typically involves some dorsal angulation at the site of the fracture.¹ This type of fracture is one of the most common fracture sites for due to osteoporotic conditions². It mostly results from a 'slip and fall' on an outstretched hand. According to World Bank report the world wide population of post menopausal women is expected to be 1.2 billion by the year 2030 and 76 % of these women would be living in the developing countries³. The incidence of Colles' fracture is 1.7 and 7.3 per 1000 person in men and women, respectively⁴. No detailed description of this disease is available in ancient text. There are so many names given for the condition associated with fracture in lower end of radius but in universal classification the colle's fracture is described as that "takes place at about an inch and a half (38 mm) above the carpal extremity of the radius" and "the carpus and the base of metacarpus appears to be thrown backward". Treatment of colle's fracture is essentially conservative. For an un-displaced fracture, immobilisation in a below- elbow plaster cast for six weeks is the standard treatment. There are so many complications of plaster treatment like impairment of circulation (tight cast), plaster sores, excessive pain, disturbed sleep, and recurrence of swelling over toes or swelling over toes or fingers, low grade fever, soakage of the plaster. For the present study cases of Colle's fracture Type I and Type II (Universal Classification) were taken for trial. There are various drugs described in Ayurvedic texts which promote the healing of fractures. Varatika Bhasma is one of them. So this trial was done to evaluate the effect of the drug in early mobilization in the management of colle's fracture.

Aims and objectives

- To decrease the period of immobilisation from 6 weeks to 4 weeks in management of Colle's Fracture Type I and Type II (universal Classification) to regain early and better movement in affected wrist joint.
- To minimize post immobilization stiffness associated with this condition.

Ethical clearance

The clinical study was in accordance with the ethical standards of the institutional ethical committee on human experimentation and with the Helsinki Declaration.

MATERIAL AND METHOD

Subjects attending the OPD and IPD of Shalya Tantra, National Institute of Ayurveda, Jaipur, Rajasthan, India were recruited in this study. All the subjects were registered by noting down their demographic profile including their age, sex, address, occupation, education, socio-economic status, marital status, addictions, dietary habits etc. After preliminary registration, patients were subjected to detailed case history taking, physical, general and systemic examinations. Ashtavidhpariksha and Dashvidhpariksha including assessment of Sharirika Prakriti (based on the features described in classical texts) etc. is noted.

Study Design

It was a randomized single blind clinical trial.

Selection of subjects

The recruited subjects fulfilling the inclusion criteria were selected for the study irrespective of sex, religion and occupation etc.

Inclusion Criteria

- Female patients having Colles' fracture Type I and Type II (Universal Classification) which can be reduced by closed reduction method with or without general anaesthesia
- Patients in the age group 30-65 years.

Exclusion Criteria

- Patients not willing to undergo trials or refused to give informed consent
- Patients below 30 years or above 65 years of age.
- Patients having TB, Hypertension, Diabetes, Cardiac disorder or some constitutional disorder
- All fracture other than colle's fracture
- Open and Multiple fractures
- Subluxation of the inferior radio-ulnar joint
- Colles' fracture having significant angulation and deformity

Grouping

The selected subjects were randomly divided and studied under two groups:

Group A

Immobilization with Plaster of Paris for 4 weeks along with Varatika Bhasma (in a dose of 375 mg in capsule form) for 6 weeks with Apakvaksheera as anupana.

Group B

Immobilization with POP for 6 weeks with Placebo (in a dose of 375 mg in capsule form) for 6 weeks with Apakvaksheera as anupana

Duration of Clinical Trial: 6 weeks

Duration of immobilization

4 weeks with oral drug and 6 weeks with Placebo

Investigations

Standard X Ray AP and Lateral view of wrist joint was taken on day 1 to diagnose the fracture, its type, severity and prognosis. The follow up X Ray was taken at the end of 4th week and 6th week. Clinical assessment for statistical analysis was done on 0 day, 28th day and 42nd day.

Follow Up

Patients followed every 15th days up to 2 month after completing treatment to review the progress of improvement or any deterioration associated with fracture Colle's.

Assessment Criteria

The improvement was assessed on the basis of relief in the cardinal sign and symptoms of disease.

Objective criteria

Table 1: Assessment of Range of Movement

	Grade
No joint movement	0
Slight movement	1
Half of the ROM	2
More than Half of the ROM	3
Good but not full ROM	4
Full ROM	5

Callus Assessment

The callus formation was assessed radiologically by taking X Ray film on 4th week of trial and compare both groups. The grading for callus assessment was done on following system.

Table 2

	Grading
Sharp or sclerotic line seen in both projections	0
Fracture line seen in only one of the projection	1
Fracture line faintly seen	2
Fracture line not seen	3

Advice for Patient

- Elevation of part as advised.
- Active finger movement.
- Watch for distal discoloration and numbness.
- Don't put or keep anything inside the cast.
- Don't wet/cut the cast.
- Immediate inform in any case of any discomfort at cast area.

Statistical Analysis

The information regarding demographic data was given in percentage. The scoring of criteria of assessment was analyzed statistically in terms of means values of B.T. (Before treatment), A.T. (After treatment), S.D. (Standard deviation) and S.E (Standard error). Paired t test and unpaired t test was carried out at level of $P < 0.05$ and $P < 0.001$.

OBSERVATIONS AND RESULTS

Observation shows that patient registered for study include maximum no. of patient in age group 51-60 years i.e. 53.33 % followed by age group 41- 50 years that include 9 patient out of 30 means 30 % of total and the least no. of patient in age group 30- 40 years that included only 5 patient that are 16.66 %. This data shows risk of Colles' fracture increases as age progresses. It was observed that the incidence of Colles' fracture was more in patients of Hindu religion, 25 patients (83.33 %) whereas 05 (16.66 %) patients belonged to Muslim community. This observation is due to the fact that the hospital where the study was carried out is situated In Hindu dominant area. Observation shows that maximum number of patients were 24 (80.00 %) belongs to Urban Habitat, followed by 8 (20.00 %) patients, belong to rural area. Probably this accurse due to the area where study was done is placed in urban area. The data shows that maximum number of patients were with secondary i.e. 11 (33.34 %), followed by 30.00 % primary, 20 % patients were have no education i.e. ill literate and 16.66 % patients were and graduate in their educational qualification. The observation shows that the patient suffers from Colles' fracture in this study 19 patient out of 30 were vegetarian and rest 11 patient i.e. 36.67 % patient were mixed dietary habits. This was observed that non vegetarian person have less prone to fracture injury than vegetarian peoples. Observation shows that maximum number of patients were 20 (66.67 %) belongs to lower class, followed by 7 (23.00 %) belong to middle class and upper middle class 2 (6.67 %), and 1 patients i.e. 03.33 % were belong to high class. Data shows that in present study in incidence of Colles' fracture was maximum in house wives 15 patients (50.00 %) followed by farmer ladies 7 patients (23.34 %), Gov. job 3 patients (10.00 %), Business men 1 patients (03.34 %), retired 2 patients (06.67 %), labourer 2 Patients (06.67 %). It was observed that in housewives the

incidence of Colles' fracture was maximum because of their nature of work. They give back seat to nutritious diet or milk intake for themselves, which leads to malnutrition or deficiency mainly of calcium which leads to Colles' fracture. During observation data shows that patient suffers from Colles' fracture include maximum no. patient having Kapha Prakruti i.e. 11 out of 30, and the second highest no is 5 out

of 30 is Vata Kapha Prakruti, then Vata and Pita Kapha have same incidence as 3 out of 30 i.e. 10 %; Vata Pita Prakruti have incidence of 13.33 % and Pita and Sannipata Prakruti have same incidence as 2 patient out of 6.67 %. That data may be due to in women's Kapha Prakruti is most common.

Table 3: Range of Movement

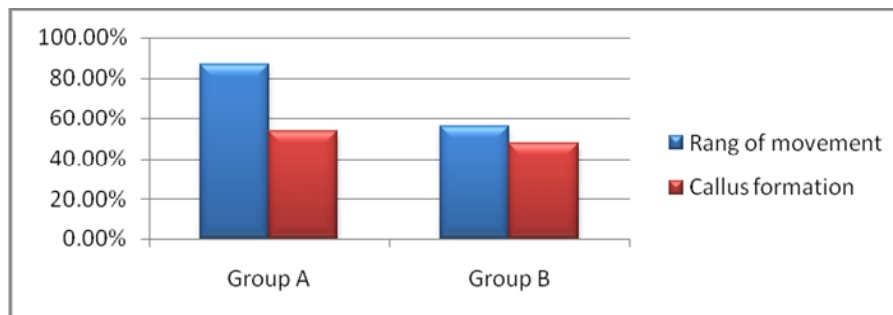
S. No.	Group	N	Mean BT	Mean AT	Mean d	% Relief	S.D.	S.E.	t value	P value	Result
1	A	15	1.933	3.7	1.86	93.107	0.941	0.243	7.4075	<0.0001	H.S.
2	B	15	2.133	3.333	1.2	56.25	0.503	0.144	8.2902	<0.0001	H.S.

Table 4: Callus Assessment

S. No.	Group	N	Mean BT	Mean AT	Mean D	% Relief	S.D.	S.E.	t-value	P value	Result
1	A	15	2.8667	1.333	1.53	53.488	0.743	0.191	7.9903	<0.0001	H.S.
2	B	15	2.8	1.466	1.333	47.619	0.723	0.186	7.1351	<0.0001	H.S.

Table 5: Inter group comparison

S.N.	Sign/Symptom	Group A	Group B	p-value	Result
1	Rang of movement	86.20 %	56.25 %	0.0286	Significant
2	Callus formation	53.48 %	47.619 %	0.463	NS



Graph 1: Inter group comparison



Image 1: X Ray wrist joint (Before treatment) in Trial group



Image 2: X Ray wrist joint (After treatment) in Trial group

DISCUSSION

In this clinical trial, maximum no. of patients was in the age group of 51-60 years i.e. 53.33 % followed by 30.00 % of the age group 41-50 years. It holds well the explanation given in contemporary science that Colles' fracture can occur at any age but is most common in people above forty years of age. The reason may be that Bones become more brittle in older ages due to osteoporosis. Older adults are more likely to fracture a bone, even with trivial trauma.

In this clinical trial of 30 patients all patients are female to make the study specific because in female Estrogen hormone is important in maintaining bone density in women. After menopause estrogen levels drops, results in loss of bone density. During the first 5 to 10 years after menopause, there is 25-30 % loss of bone density in females. This post menopausal osteoporosis is responsible for increase incidence of Colles' fracture in females.

The age group selected for the study was 30- 60 years so all the patient selected for the trial was married. In general marital status is not responsible for these fractures.

It was observed that the incidence of Colles' fracture was more in patients of Hindu religion, 25 patients (83.33 %) whereas 05 (16.66 %) patients belonged to Muslim community. This observation is due to the fact that the hospital where the study was carried out is situated In Hindu religion dominant area.

Observation show that maximum number of patients was 24 (80.00 %) belongs to Urban Habitat, followed by 6 (20.00 %) patients, belongs to rural area; may be due to the geographical reasons.

In the present study incidence of Colles' fracture was maximum in house wives (50.00 %) followed by farmer or rural (23.36 %), Gov. Job (10 %), businessmen (3.34 %), retired employee (6.67 %) labourer 2 (6.67 %). So number of incidence of Colles' fracture is different in patient with different occupation. This may be due to the number of patients included in the study was limited and due to random selection of patient. But number of house wives was significantly higher than others. This may be due to their nature of work. Women use to work for long hours in wet surface, like in bathroom which puts lot of chance to slip. Secondly due to lack of nutritious diet and due to hormonal imbalance which lead to Osteoporosis in them.

In this study maximum no.11 out of 30 was (36 %) of the patients were from Kapha Prakruti. This is may be due to that mostly female have Kapha Prakruti and those due to less active nature, gaining weight and after falling more chance of fracture. The second highest no. is Vata Kapha Prakruti 4 out of 30 people as well as they may have more fragile bones due to Vata. These might be reasons that fractures are more reported in Vata, Kapha Prakruti people.

Observation shows that maximum number of patients were 20 (66.67 %) belongs to lower class, followed by 7 (23.00 %) belong to middle class and 2 (6.67 %) belong to upper middle class and 1 (3.33 %) patients was belong to high class. Here one thing observed that females from poor class have more incidences to fracture due to more exposure to work or might be due to poor nutrition.

The data shows that maximum numbers of patients were secondary education (33.33 %), followed by 30.33 % patient with primary education, 20 % patients with illiterate and 16.66 % patients graduate. Nothing specific can be drawn from this observation. To correlate education with the

occurrence of disease, a bigger sample should be drawn from population for study.

Observation shows that maximum of patients were Vegetarian (63.33 %), followed by patients with mixed diet (36.67 %). Nothing specific can be drawn from this observation.

During assessment of the patient range of movement after 6 week in group A and B relief was 86.20 %, ($P < 0.001$), 56.25 % ($P < 0.001$) respectively. This can be absolutely attributed to the early discontinuation of immobilisation in Group A. In this study callus formation was better observed in Group A than in group B. This can be explained by the logic that Varatikabhasma exerts influence both on the organic and mineral phase of fracture healing. Vararatka Bhasma is highly crystalline calcium carbonate in the calcite form with presence of trace elements like Magnesium, Aluminium, Potassium, Iron and Zinc resulting in early regeneration of all connective tissues of mesenchyma origin, namely the fibroblasts, the chondroblasts and osteoblasts involved in the fracture healing and quicker mineralization of the callus. The action of trial drug Varatika Bhasma could be explained on the basis of their Rasa, Guna, Veerya and Vipaka and pharmacological action. Varatika Bhasma has Sandhaniya, Raktaprasadaka and Rarayan properties. It has Katu Rasa, Rukhsa and Tikshna Guna, Ushna Veerya and Katuvipaka hence kaphashamak nature which is responsible for the reduction of pain, tenderness and swelling around fracture site. Also, Varatikabhasma contains Phosphate, Fluoride and Carbonate of Calcium, Magnesium and Phosphate of Manganese. The analysis of Kapardika Bhasma shows that the overall process of formation of Kapardika Bhasma involves decarbonation of calcium carbonate in aragonite form and reformation of the calcium carbonate in the calcite form. This transformation occurs via formation of calcium hydroxide and calcium oxide as the intermediates. Kapardika Bhasma is thus highly crystalline calcium carbonate in the calcite form with presence of trace elements like Magnesium, Aluminium, Potassium, Iron and Zinc.⁵ Varatika Bhasma exerts influence both on the organic and mineral phase of fracture healing. The components of Varatika Bhasma showed a marked influence on fracture-healing. The probable mechanism of action in fracture healing can be attributed to the stimulation of the metabolism and increased uptake of the calcium, sulphur, and strontium by the osteoblasts. These trace elements acts as antagonists to the glucocorticoid receptor and promotes fracture healing. Varatikabhasma mobilizes fibroblast and chondroblasts to an injured tissue and promotes fracture healing. The anabolic steroidal component of Varatika Bhasma showed a marked influence on the rate of fracture healing by influencing early regeneration of all connective tissues of mesenchyma origin, namely the fibroblasts, the chondroblasts and osteoblasts involved in the fracture healing and quicker mineralization of the callus. As already discussed in observation and result section that the drug Varatika Bhasma possess potential of promoting Fracture healing by improving the rate of callus formation and hence relief in pain, tenderness, reduction in swelling. Early and better regain in the range of movement of wrist joint can be attributed to early mobilization by removing POP cast after 4 week instead of immobilisation of 6 weeks. These results may be due to its Chemical composition which include large amount of calcium, Iron, Manganese, Potassium, Glycoside, Flavonoids and lot of other Trace element which Play a key role in enhancing

fracture healing. But for the validation and establishment of this fact study with larger sample size along with the laboratory assessment of markers of fracture healing is required.⁶

CONCLUSION

Therefore, it can be concluded that Varatika Bhasma is supportive in the management of Colles' fracture as it is safe, cost effective and free from any side effects.


Recommendations

- Study should be carried out in large sample size.
- The various formulation discussed in our ancient samhitas should be tried for their clinical applicability.
- The bio-chemical, Histological studies to be carried out to assess the efficacy of Varatika Bhasma in enhancing bone healing.
- The study should be conducted for a longer duration so as to know the lasting of the clinical effects.

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