ABSTRACT

Colle's fracture is a fracture at the distal end of the radius, at 'Colle's fracture', and is particularly common in women because of post menopausal osteoporosis. It mostly results from a 'slip and fall' on an outstretched hand. For an undisplaced fracture, immobilisation in a below-elbow plaster cast for six weeks is the standard treatment. For displaced fractures, the standard method of treatment is manipulative reduction followed by immobilisation in Colle's cast.

Few traditional practitioners specifically dealing with fractures, called 'Bone setters', have been effectively using herbal drugs over many centuries. Many of these drugs are simple, easily available, cost effective and potent. The scientific evaluation of such drugs along with their fundamental principles is essential for their universal acceptance. Hence in this study an attempt is made to prepare a drug about which there are textural references regarding Asthibhagna sandhan. Through clinical trial in the present study it has been tried to prove the efficacy of Asthishrankhala (Cissus quadrangularis Linn.) for early mobilization in the management of Colle's fracture. There are so many complications of plaster treatment like as impairment of circulation(tight cast), plaster sores, excessive pain, disturbed sleep, recurrence of swelling over toes or swelling over toes or fingers, low grade fever, soaking of the plaster. To overcome these problems an Ayurvedic approach has made. There are various fractures healing promoter drugs described in Ayurvedic books and Asthishrankhala is one of them. Hence in this study an effort was done to evaluate the effect of the drug in early mobilization in the management of Colle's fracture.

INTRODUCTION

Colle's fracture is a fracture at the distal end of the radius, at its cortico-cancellous junction (about two cm from the distal articular surface) with typical displacement. It is the commonest fracture in people above forty years of age, and is particularly common in women because of post menopausal osteoporosis. For an undisplaced fracture, immobilisation in a below-elbow plaster cast for six weeks is the standard treatment. For displaced fractures, the standard method of treatment is manipulative reduction followed by immobilisation in Colle's cast. Few traditional practitioners specifically dealing with fractures, called 'Bone setters', have been effectively using herbal drugs over many centuries. Many of these drugs are simple, easily available, cost effective and potent. The scientific evaluation of such drugs along with their fundamental principles is essential for their universal acceptance. Hence in this study an attempt is made to prepare a drug about which there are textural references regarding Asthibhagna sandhan (reduction of fracture). Through clinical trial in the present study it has been tried to prove the efficacy of Asthishrankhala (Cissus quadrangularis Linn.) for early mobilization in the management of Colle's fracture. There are so many complications of plaster treatment like as impairment of circulation(tight cast), plaster sores, excessive pain, disturbed sleep, recurrence of swelling over toes or swelling over toes or fingers, low grade fever, soaking of the plaster. To overcome these problems an Ayurvedic approach has made. There are various fractures healing promoter drugs described in Ayurvedic books and Asthishrankhala is one of them. Hence in this study an effort was done to evaluate the effect of the drug in early mobilization in the management of Colle's fracture.

MATERIALS & METHODS

Selection of Patient: 30 clinically diagnosed Patients of Colles fracture have been selected from the OPD & IPD units of PG Department of Shalya Tantra of NIA, Jaipur.
A) Age group: Between 30-70 yrs
B) Sex: Either Sex
C) Study Design: Randomized
D) Study Center: Uni-central
E) Sample Size and Method: Total 30 Patients.

Grouping of Patients

Trail Methodology- The modern methodology for trial & statistic design was suitably adopted for the present study.

Simple Random Sampling: The selection of patient for the present study was done in a randomized design. Here, the every unit of the population had an equal chance of being selected, which sometimes called as 'unrestricted random sampling'. In this study, those patients were selected, who fulfilled the following criteria.

a) Who had given informed consent. The patients were explained about the purpose, procedures and possible danger of the trial.
b) Who were eligible for the trial or included under the inclusion criteria.

30 registered, clinically diagnosed and confirmed patients of Colle’s fracture were selected for the present clinical trial and randomly divided in following three groups of 10 patients each.

GROUP-A: Drug used: Asthishrankhala lepa (External Application)
Drug Dosage: 15 gm churna (powder) mixed with water, after every 24 hrs lepa was changed.
Site of lepa: At the fracture site and 3cm above and below the fracture site
Preparation method: The lepa was prepared daily with water.

GROUP-B: Drug used: Asthishrankhala churna (powder)
Drug Dosage: 3-4 gm BD, with Godugdha (Cow’s milk).
Preparation method: The churna was prepared in NIA pharmacy.
GROUP-C: Drug used: Asthishrankhala churna, Asthishrankhala lepa

Drug administration: As mentioned above for both, Asthishrankhala churna and Asthishrankhala lepa. The churna was administered internally, whereas Asthishrankhala lepa was applied externally

Duration of Clinical Trial
Duration of immobilization - 4 weeks
Duration of oral drug administration - 6 weeks
Duration of lepa - 2 weeks

i) Inclusion Criteria-
- Patients in the age group 30-70 yrs of either sex.
- Patient is willing for trail and ready to give informed consent.
- Patients having Colle’s fracture which can be reduced by closed reduction method with or without general anesthesia.

ii) Exclusion Criteria-
- Patients not willing to undergo trials or refused to give informed consent.
- Patients below 30 yrs or above 70 yrs of age.
- Patients having TB, Hypertension, Diabetes, Cardiac disorder or some constitutional disorder.
- All fracture other then Colle’s fracture.
- Open fracture.
- Multiple fractures.
- Subluxation of the inferior radio-ulnar joint.
- Colle’s fracture having significant angulation and deformity.
- Fracture required open reduction and internal fixation
- Institutional Ethical Committee permission obtained (Reg. No) – RAU/10/2114
- Rajasthani University Registration No - RAU/Aca./400/09-10

Investigations
X- RAY - X ray 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 third week & six week.

Observation of Patient during Treatment
Standard treatment for Colle’s fracture –Immobilisation for six weeks
Duration of study: 6 weeks.
Time interval for assessment of progress: Weekly.
Presentation of observation: Through tables & Graphs.

Assessment Criteria
The improvement in the patient was assessed mainly on the basis of relief in the cardinal sign & symptoms of disease.

A) Subjective criteria
1) Pain
2) Swelling
3) Loss of function:

B) Objective Criteria
1) Tenderness:
2) Callus assessment:

OBSERVATIONS AND RESULTS
The observations and results in all the three groups have been made in the present study.

Demography of General profile: It includes incidence of age, sex, marital status, education, occupation, economic status etc. (Table 1)

Results of therapeutic Trial
It includes results on various parameters in all three groups of 30 patients registered for current clinical trial to evaluate the efficacy of Asthishrankhala in the management of Colle’s fracture.

While anchoring the study, total 35 patients were registered on the basis of inclusion criteria from IPD & OPD of NIA. Among all the patients enrolled for the study 5 patients failed to complete the study due to non-compliance of the protocol or were withdrawn due to various reasons. Remaining 30 patients were assorted in to 3 groups.

Table 1: Demographic observations of total registered patients

<table>
<thead>
<tr>
<th>Observations</th>
<th>Predominance</th>
<th>No. of Pts</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>61-70 years</td>
<td>13</td>
<td>43.33%</td>
</tr>
<tr>
<td>Sex</td>
<td>Female</td>
<td>20</td>
<td>66.66%</td>
</tr>
<tr>
<td>Religion</td>
<td>Hindu individuals</td>
<td>27</td>
<td>90%</td>
</tr>
<tr>
<td>Habitat</td>
<td>Urban area</td>
<td>22</td>
<td>73.33%</td>
</tr>
<tr>
<td>Marital status</td>
<td>Married</td>
<td>28</td>
<td>93.33%</td>
</tr>
<tr>
<td>Educational status</td>
<td>Illiterate</td>
<td>13</td>
<td>43.33%</td>
</tr>
<tr>
<td>Socio-economic status</td>
<td>Lower Middle class</td>
<td>14</td>
<td>46.66%</td>
</tr>
<tr>
<td>Occupation</td>
<td>House wife</td>
<td>17</td>
<td>56.67%</td>
</tr>
<tr>
<td>Dietary habits</td>
<td>Vegetarian</td>
<td>17</td>
<td>56.66%</td>
</tr>
</tbody>
</table>

Table 2: Statistical Analysis of Assessment of Pain In Group A, B & C

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>GROUPS</th>
<th>N</th>
<th>Mean B.T</th>
<th>Mean A.T</th>
<th>Mean Diff</th>
<th>Mean %</th>
<th>S.D</th>
<th>S.E</th>
<th>t Value</th>
<th>p Value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>GROUP A</td>
<td>10</td>
<td>1.4</td>
<td>0.8</td>
<td>0.6</td>
<td>42.86</td>
<td>0.51</td>
<td>0.16</td>
<td>3.67</td>
<td>&lt; 0.005</td>
<td>S</td>
</tr>
<tr>
<td>2</td>
<td>GROUP B</td>
<td>10</td>
<td>1.5</td>
<td>0.4</td>
<td>1.1</td>
<td>73.34</td>
<td>0.56</td>
<td>0.17</td>
<td>6.12</td>
<td>&lt; 0.001</td>
<td>HS</td>
</tr>
<tr>
<td>3</td>
<td>GROUP C</td>
<td>10</td>
<td>1.3</td>
<td>0.2</td>
<td>1.1</td>
<td>84.62</td>
<td>0.56</td>
<td>0.17</td>
<td>6.12</td>
<td>&lt; 0.001</td>
<td>HS</td>
</tr>
</tbody>
</table>
DISCUSSION

Demographic observations

Age: In this clinical trial, maximum no. of patients was in the age group of 61-70 yrs. i.e. 43.33% followed by 23.33% of the age group 51-60 yrs. It holds well the explanation given in contemporary science that Colle’s 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\(^6\). Older adults are more likely to fracture a bone, even with trivial trauma.

Sex: In this clinical trial 20 patients (66.67%) were reported to be females and 10 (33.33%) patient were males, which suggest the incidence of Colle’s fracture is more common in females than the males. Estrogen hormone is important in maintaining bone density in women. During menopause estrogen levels drops, results in loss of bone density. During the first five 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 Colle’s fracture in females.

Marital status: Observation shows that maximum number of patients 28 (93.33%) were married. 2 (6.67%) patients were unmarried. This is the reflexion of age criteria settled for inclusion of pts. In general marital status is not responsible for these fractures.

Occupational Status- In the present study incidence of Colle’s fracture was maximum in house wives (56.67%) followed by govt job employee (13.33%), farmer (10%), businessmen (6.67%), retired employee (6.67%) Labourer 1 (3%) & student (3%). So number of incidence of Colle’s 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 this leads to osteoporosis in them.

Prakruti- In this study almost half (47%) of the patients were from Vata-Pitta Prakruti. This is may be due to active nature of Vata Prakruti people as well as they may have more fragile bones. These might be reasons that fractures are more reported in Vata Prakruti people.

Signs and symptoms
The most common signs and symptoms observed in fractured patients were pain, swelling and tenderness. To assess these signs and symptoms they are graded as per their characters. The aim of this clinical study was to assess the effect of Asthishrankhala on fracture healing, pain & swelling tenderness. After 6 weeks treatment % relief in pain in group A, B and C was 42.85 (p< 0.005), 76.92 (p< 0.001) and 84.61(< 0.001) respectively. Hence these observations indicate that Asthishrankhala has analgesic activity.

There was drastic reduction of swelling after administration of drug. After 6 weeks treatment % reduction in swelling in group A, B and C was 35.71 (p< 0.01), 76.92 (p< 0.001) and 64.28 (p< 0.001) respectively. These results indicate the efficacy of drug in reduction of swelling.

There was also reduction in tenderness after administration of drug. After 6 weeks treatment % reduction in tenderness in group A, B and C was 38.09 (p< 0.001), 27.27 (p< 0.01) and 40 (<p< 0.001) respectively. These results indicate the efficacy of drug in reduction of tenderness. Effect on these signs and symptoms of inflammation indicate about anti-inflammatory nature of Asthishrankhala.

Callus formation, a part of initial fracture healing is influenced by various factors. Age is one of the important factors that influence callus formation. In younger patients callus formation and fracture healing is early as compare to the adults and elderly. This might be due to the increased vascularity as well as ability of cells of periosteam to differentiate more in younger individuals. In this study although most of the patient were older age group yet callus formation was good in these older age patient due to Asthishrankhala. Callus formation is also dependent on part of bone involved. Callus formation is more in diaphyseal fractures than in metaphyseal fractures. As this study was specified to fracture of lower end of radius where callus formation should be poor but due to Asthishrankhala callus formation was also good in this part of bone. In group C Callus formation was good in comparison to group A & B. In this study grading of callus formation was not done because it was very difficult to grade callus formation radiologically.

Action of Drug
In the present study the action of trial drug Asthishrankhala could be explained on the basis of their Rasa, Guna, Veerya and Vipaka & pharmacological action. Asthishrankhala has sandhianhi, Raktaprasadaka nature. It also has Ushna Veerya nature which is responsible for the reduction of the swelling around fracture area as well as helps to penetrate it in to local tissue for action. Asthishrankhala kaphavata-shamaka nature reduces the local oedematous residue. Due to Madhura Rasa property of Asthishrankhala on local vata dosha shama takes place and pain is reduced. Chemically Asthishrankhala has calcium oxalate, carotene and ascorbic acid which are responsible for early callus formation.

Pharmacological action:
Asthishrankhala contains some anabolic and phytogenic steroids like Ketosteroids, silisterol, alpha amayrin, alpha ampyrone and tetracyclic treterpenoids. These anabolic and steroidal components showed a marked influence on fracture-healing. Ketosteroid acts as antagonists to the glucocorticoid receptor and promotes good bone health. It mobilizes fibroblast and chondroblasts to an injured tissue and enhances regeneration. The anabolic steroidal component of Asthishrankhala showed a marked influence in 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 healing and quicker mineralization of the calccus. The probable mechanism of action in fracture healing is believed in part to be due to the stimulation of the metabolism and increased uptake of the calcium, sulphur, and strontium by the osteoblasts. Asthishrankhala exerts influence both on the organic and mineral phase of fracture healing.

CONCLUSION
From the present study entitled “Role of Asthishrankhala in early mobilisation in the management of Colle’s fracture” following conclusions could be drawn:
1. Colle’s fracture is not described exactly in Ayurvedic text and difficult to co-relate with any type of bhangna.
2. All the three groups gave statistically significant results but intergroup comparison reveals that group C has an upper edge in relieving the symptoms.
3. Females showed their predominance for the disease under trial.
4. The incidence of Colle’s Fractures was found to be more in age group of 51 to 70 years.
5. Patients with Vata dominating prakirti are more likely to suffer.
6. No side effects have been reported by the patients during the course of treatment.
7. The sample size was very small to generalize the result.
8. The study was conducted for a shorter duration i.e. for six weeks, which is not sufficient to assess the long term efficacy of the therapy.
9. Swelling, pain, tenderness are the definite evidence for fracture. However radiology has very important role to play with diagnosis of fracture.
10. Pain and swelling are the two important and troublesome symptoms of fracture which need an immediate clinical attention.
11. The drug has a beneficial effect in reducing symptoms and bone healing. To say authoritatively Asthishrankhala...
had any added advantages, further studies should be carried out separately with the help of bio-chemical analysis.

Therefore, it can be concluded that asthishrankhala is effective in the management of colle’s fracture as it is safe, cost effective and free from any side effects.

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