TO STUDY THE EFFECT OF (HEN’S EGG SHELL POWDER) KUKKUTANDATWAK BHASMA IN FRACTURE MANAGEMENT WITH SPECIAL REFERENCE TO LONG BONES

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INTRODUCTION

Ayurveda (ayu-life; veda- knowledge of) is a Sanskrit word that literally translates as the "wisdom of life" and knowledge of longevity. The oldest written of Ayurvedic principles are found in the Rig-Veda. The fundamentals are then laid out in several major treatises including the texts from Charaka, Sushruta and Vagbhata.

Shalya Chikitsa (Surgery)

Surgery was principally pioneered by Ayurveda. Shalya Chikitsa is the significant branch of Ayurveda science. The name of the Sage Sushruta is synonymous with surgery, evident from his treatise Sushruta Samhita.

The original text of Sushruta has a detailed discussion of the exhaustive range of surgical methods which is inclusive of methods of how to deal with various types of tumors (arbud, granthi, etc), internal and external injuries (abhayantar and bahya vrana), fracture of bones (bhagna), complication during delivery (moodhgarbh) and obstruction in intestinal loops.

Sushruta was the first surgeon to develop cosmetic surgery in Ayurveda. In Ayurvedic practice, the fracture of bones and treatment of bones was first mentioned in Sushrut Samhita, Chikitsa sthan and Nidan sthan from the surgical management in 1500 BC. Fracture is termed as “Bhagna” in Ayurveda which means break in continuity of bones. Bhagna is of two types: Sandhi mukta or dislocation and Kandabhagna i.e. bone fracture.
Modern Perspective
Fractures can happen in variety of ways, but three common causes are:

- When the force on the bone is too large and occurs suddenly as in road traffic accidents and fall etc.
- When the force on the bone is chronic and repetitive e.g. prolonged standing in policeman, nurses, surgeons, military personels.
- When the natural resistance of the bone is eroded by disease process (e.g. Tumor, osteoporosis, infection.) that the bone succumbs injury and breaks. And its surroundings are also injured including soft tissues, muscles, ligaments.

PURPOSE OF STUDY
The main complaint of many musculoskeletal disorders is pain related to the mal-united, nonunion of fractures and osteoporosis.

Its high prevalence, especially in the elderly and the high rate of disability related to the disease and make it a leading cause of disability in the elderly.

Fracture related to trauma, being the major issue in todays fast moving lifestyle.

It is due to heavy traffics, bad road qualities, and high speeding vehicle.

Fracture is a complete or incomplete break in the continuity of bone.

Ayurvedic texts have explained fracture as loss in continuity of the bone due to the external pressure. However, the incidence of long bone fracture seems to be on rise, so it needs to be special care. The management of long bone fracture runs through the basic principles of fracture management, e.g.-


Along with all the basic principles, more important is administration of NSAID’s and Calcium supplements which helps fast recovery. In the ancient treatise many compounds of were available for fracture healing. With reference to that, Rasa Tantra Saar, an indigenous compound named Kukkutandatwak Bhasma is also accepted as the treatment of Fractures (Bhagna Sandhan). Hence, the present study is proposed to see the effect of Kukkutandatwak
Bhasm in Fracture management of Long bones, as no much detail data is available for Kukkutandatwak bhasma in long bone fracture management.

PREVIOUS WORK DONE

- Dalabi M.S, A detailed evaluation Kukkudandatwak Bhsma with Special reference to its Ayurvedic Manufacturing process including shodhana and Marana, Pune (1994-95)

In this clinical study Kukkutandatwak Bhasm has shown statistically significant improvement in white discharge, backache, itching, anaemia, weakness and urinary tract infection.

Preparation and Comparative Chemical evaluation of Kukkutandatwak Bhasm samples without Hingula" by Dr. Sheena and Dr. J. Dinesh Nayak, Dr. Sathyanarayan. "Dept of Rasa Shastra" 2009-2010, Muniyal Institute of Ayurveda Medical Science, Manipal, (Rajiv Gandhi University of health Sciences, Bangalore, Karnataka).

INFERENCEx

The above work done explains the effect of Kukkutandatwak Bhasma in other gynecological disorders, but it also explains good role in bone healing, so, I have taken this drug to assess the efficacy of Kukkutandatwak Bhasma in fracture management.

Ayurvedic Properties of Kukkutandatwak Bhasma

1. Rasa (Taste):   Madhura (Sweet), Tikta (Bitter)
2. Guna (Main Qualities):   Laghu (Light), Mridu(Soft)
3. Veerya(Potency):   Ushna (Hot)
4. Vipak (Resultant):   Madhura (Sweet)
5. Prabhav(Theurapetic effect): Rejuvination.

7. Effect on Organs: Bones and joints


**HYPOTHESIS**
Kukkutandatwak Bhasma is effective in the fracture management of long bones.

**AIM**
To evaluate the effect of Kukkutandatwak Bhasma in fracture management of long bones.

**OBJECTIVE**
To study the efficacy of Kukkuandatwak Bhasma in long bone fractures.

**MATERIALS**
A). Eligible patient as per criteria,
B). Kukkutandatwak Bhasma,
C). Calcium Carbonate.
D). Miscellaneous (Operative Procedures: Nailing, Plating, Plaster of Paris)

**AUTHENTIFICATION**
The Kukkutandatwak Bhasma available in the local market of Pune and Mumbai will be authenticated from the pharmacy.

**STANDARDIZATION**
Standardized Certification will be obtained.
Standardization of Bhasma formulations is essential in order to assess the quality drug based on the concentration of their active principles, physical, chemical, phytochemical standardization parameters.

All the tests will be carried out as per WHO guidelines and Ayurvedic Pharmacopeia of India(API).

**CLINICAL STUDY**

**STUDY DESIGN**
An open clinical trial study will be done.
A comprehensive case paper is attached at the end of Synopsis.
METHODOLOGY
- The study is a randomized clinical study in which 30 patients will be selected on the basis of simple random sampling (SRS) procedure and will be divided in two equal groups.
- Consent will be obtained from the patients who are registered for trial.
- Patients’ relatives will be informed about the purpose and schedule of study.
- Written informed consent will be obtained from the patient or patients’ relative before screening for the eligible criteria.

SAMPLE SIZE
Completed 30 patients, Satisfying inclusive and exclusive criteria selected and divided equally into two groups of 15 patients each as trial group and control group.

GROUPING AND DOSAGE SCHEDULE
- 30 patients were taken for the study dividing into two groups, 15 each.
- Group A was trial group and Group B was control group.

Group-A (Trial Group)

<table>
<thead>
<tr>
<th>Sample size</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug</td>
<td>Kukkandatwak Bhasm</td>
</tr>
<tr>
<td>Dose</td>
<td>One ratti (120 mg)</td>
</tr>
<tr>
<td>Procedure</td>
<td>Internal medication</td>
</tr>
<tr>
<td>Time</td>
<td>Morning before breakfast</td>
</tr>
<tr>
<td>Method</td>
<td>Oral administration</td>
</tr>
<tr>
<td>Duration</td>
<td>21 days</td>
</tr>
<tr>
<td>Total period of study</td>
<td>21 days</td>
</tr>
</tbody>
</table>

ANUPAN: Madhu (Honey). Ref: Rastantrasar.

Group B (Control)

<table>
<thead>
<tr>
<th>Sample size</th>
<th>15</th>
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<tbody>
<tr>
<td>Drug</td>
<td>Calcium Carbonate</td>
</tr>
<tr>
<td>Dose</td>
<td>500 mg bid</td>
</tr>
<tr>
<td>Procedure</td>
<td>Internal medication</td>
</tr>
<tr>
<td>Time</td>
<td>Morning before breakfast, before dinner.</td>
</tr>
<tr>
<td>Method</td>
<td>Oral administration</td>
</tr>
<tr>
<td>Duration</td>
<td>21 days</td>
</tr>
<tr>
<td>Total period of study</td>
<td>21 days</td>
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</table>

ANUPAN: Water.
STUDY PLACE

INCLUSIVE CRITERIA
- Only those patients who fulfilled the eligibility criteria were recruited.
- Selected patients were randomly allocated.
- Patients with long bones fracture like humerus, radius, ulna, femur, tibia and fibula were be considered for the study.
- Patient selection done irrespective of sex, religion, socio-economic Class.
- All patients above balya-awastha, like from age group 16 years to 50 years.
- Patients with ORIF will also be selected for the study.
- Fracture with history of trauma.
- Fractures diagnosed by radiographs.

EXCLUSION CRITERIA
- Patients below the age of 16 years.
- Patients having other systemic pathology like Tuberculosis, malignancy.
- Patients having fractures of Small bones.

DROP-OUTS
If any patient having allergy to Kukkutandatwak Bhasma, that patient were not be considered and were dropped out.

ASSESSMENT CRITERIA WITH GRADATION
The clinical assessment was done with the initial findings through clinical and radiological statements and compared with the result of changes on 10th and 21st day.

PAIN: Assessed by medical research council grading of pain.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal (No Pain)</td>
</tr>
<tr>
<td>+</td>
<td>Mild (Localized feeling of pain during movement, but not during rest)</td>
</tr>
<tr>
<td>++</td>
<td>Moderate (localized feeling of pain during rest, but not disturbing sleep)</td>
</tr>
<tr>
<td>+++</td>
<td>Severe (localized continuous feeling of pain, radiating and not relieving by rest)</td>
</tr>
</tbody>
</table>
TENDERNESS: Elicited in accessible cases on first day, 10th day and 21st day.

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>0</td>
<td>No Tenderness</td>
</tr>
<tr>
<td>+</td>
<td>Mild Tenderness</td>
</tr>
<tr>
<td>++</td>
<td>Moderate Tenderness</td>
</tr>
<tr>
<td>+++</td>
<td>Severe Tenderness</td>
</tr>
</tbody>
</table>

SWELLING: In Accessible cases.

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<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>0</td>
<td>No Swelling</td>
</tr>
<tr>
<td>1</td>
<td>Swelling</td>
</tr>
</tbody>
</table>

RADIOGRAPH: Visible callus on X-ray.

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<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>Callus absent</td>
</tr>
<tr>
<td>1</td>
<td>Callus Present</td>
</tr>
<tr>
<td>2</td>
<td>Healing of Fracture</td>
</tr>
</tbody>
</table>

TREATMENT /PROCEDURE

- Initially all the patients treated with Reduction and immobilization as per requirement e.g.: Intra-medullary Nailing, Plaster of Paris, K-wire fixation.
- During the treatment, the patients were regularly observed. The changes were noted in the specially prepared case sheet.
- The observation was analyzed on the basis of assessment parameters (both subjective and objective) before, during and after treatment on 0th, 10th and 21st day.
- Finally the result was statistically evaluated for its significance.

INVESTIGATION

Following investigations were carried out before and after treatment.
X-ray of the fractured limb on the day of injury and on 21st day post injury.

OBSERVATIONS

Observation were drawn on the basis of collected data with the help of chart and tables.

STATISTICAL ANALYSIS

Appropriate Statistical method was used.

DISCUSSION

Discussion is drawn on the basis of observations and results.
CONCLUSION
On the basis of collected data appropriate conclusion is drawn.

EXPECTED OUTCOME
Kukkutandatwak Bhasma increases the calcium levels in fracture of long bones leading to good callus formation.

BIBLIOGRAPHY/REFERENCES
1. An alphabetical bibliography is prepared of the list of the relevant text and authors whose work has been consulted and is included at the end of the dissertation.
2. Rasa Tantra Saar.
4. Sushrut Samhita, Nidan sthan 15 Chapter.
5. ijrap.com.
6. nacc slogan: “sunday ho ya monday, roj khao andey”.