Evaluation of the effect of Panchatikta Ksheer Basti in the management of asthikshaya with special reference to Osteoporosis & Osteopenia.

KEYWORDS
Panchatikta Ksheer Basti, Asthikshaya, Osteoporosis, Osteopenia

INTRODUCTION
Asthikshaya is not exactly a disease occurring due to Dosha-Dushya Sammurchhana but a condition where because of degenerative changes in Asthi, vata dosha residing in asthi vitiates giving rise to symptoms like bone & Joint pain. It can be compared with osteoporosis & Osteopenia where there is decrease in bone mass leading to increased bone fragility and susceptibility to fractures. Osteoporosis and Osteopenia both in fact represent the same degenerative pathology with difference in severity gradations hence both can be compared with asthikshaya. Around the world 1 in 3 women and 1 in 5 men over the age of 50 suffer an osteoporotic fracture. In fact a bone will break every 3 seconds because of disease. Multiple research studies have been carried out till date to find out effective treatment to cure and prevent Osteoporosis but there are many restrictions in finding the solution which is effective and still safe even after long term use. Hence the present study was designed to study the efficacy of Panchatikta Ksheer Basti in the management of asthikshaya w.r.t. osteoporosis and osteopenia.

AIM AND OBJECTIVES
AIM:
To evaluate the efficacy of Panchatikta ksheer basti in the management of Asthikshaya with special reference to osteoporosis & Osteopenia.

OBJECTIVES:
- To study the conceptual and clinical aspects of asthikshaya, osteoporosis & Osteopenia.
- To assess the role of Panchatikta Ksheer basti in the management of asthikshaya.
- To assess the effect of Panchatikta Ksheer basti in the management of asthikshaya (with special reference to osteoporosis) in the terms of the effect on the bone density.

MATERIALS AND METHODS
MATERIALS
Drug used: Panchatikta Ksheer basti

METHOD:
PANCHAIKTA KSHEER BASTI :-
- Form: Ksheer basti
- Dosage: 180ml
- Kala : Pratah (morning after breakfast), once a day
- Duration of Trial: 30 days
- Route of Administration: per rectal

Contents:
Since there is no direct reference about the contents and quantities of the drugs used for ksheer basti, wherever required previous research work done by other scholars has been referred.

1)Ksheerpaka dravya:
- Guduchi
- Nimba
- Vasa
- Kanchnar
- Patanjali

2)Prakshep dravya:-
Goghrut (Cow’s ghee) 30 ml
Til Tailam (Sesame oil) 30 ml

Preparation of the basti:
Panchatikta Gana + Milk + Water + Ggriita + Til Tail
Thoroughly mixed

Panchatikta Ksheer Basti
ringe attached to Rubber Catheter with its tip lubricated and inserted per rectum in left lateral position of patient.

**Follow up:** Basti follow-up daily for 30 days. Criteria assessment on Day 1, 15, 30, 60 & 90.

**Note:** Panchatikta ksheer Basti was prepared fresh daily for each patient.

Panchatikta powder, Ghee & Oil were taken from the same batch to maintain the quality.

**METHOD:**
Selection criteria-
- 30 patients clinically diagnosed as asthikshaya & with low BMD T-score were selected from O.P.D irrespective of sex, religion, education, occupation, economical status etc.
- Informed written consent was obtained from each & every patient.

Inclusion criteria
- Patient presenting classical signs and symptoms of Asthikshaya.
- Age 25 to 75 years
- Patients having BMD t-score <-1.0.

Exclusion criteria
Patients of osteoporosis or osteopenia suffering from
- Any congenital, structural deformities, Severe anemia, veneral diseases, Hepatitis, HIV-AIDS, Malignancies, Tuberculosis, Cardiac disorders, renal failure, mental and infectious disorders
- Pregnancy
- who requires surgical intervention

Withdrawal criteria
The patient were withdrawn from the trial who
- had occurrence of serious adverse effects
- was non-cooperative
- were violating the protocol

**INVESTIGATIONS:**
**BONE MINERAL DENSITY (BMD):**
WHO has defined osteoporosis on the basis of BMD t-score. Hence here Bone mineral density was done before the treatment and 2 months after the treatment. Estimated heel BMD was obtained from measured Broadband Ultrasound Attenuation and Speed of sound and scoring was done as per following standards.

**Table 1- Bone Mineral Density (‘t’-score) here**

Criteria of assessment
The effect of therapy was assessed on the basis of changes observed in following parameters.

**Subjective parameters:**
Asthishool (pain in bones)
Sandhishtool (pain in joints)
Katishool (low back ache)
Roukshya (Dryness)
Shrama (Weakness)
Keshapatan (Hair Fall).

**Objective parameter:**
BMD t-score.

**Asthishool:**
Oxford pain chart was used for the assessment of asthishool.

<table>
<thead>
<tr>
<th>Severity of pain measurement</th>
<th>Pain relief measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Severe-03</td>
<td>1. Complete-00</td>
</tr>
<tr>
<td>2. Moderate-02</td>
<td>2. Good-01</td>
</tr>
<tr>
<td>3. Mild-01</td>
<td>3. Moderate-02</td>
</tr>
<tr>
<td>4. No pain-00</td>
<td>4. Slight-03</td>
</tr>
</tbody>
</table>

**Explanation**
1. Severe pain-Patient is unable to do any movement.
2. Moderate-Movements are possible but continuous pain during movement.
3. Mild-Pain precipitating time to time.

**Shrama:**
For the assessment of shrama following scale has been used.
- Grade 0: no shrama
- Grade 1: not able to perform strenuous activity
- Grade 2: not able to perform moderate activity
- Grade 3: cannot perform moderate activity but can perform mild activity
- Grade 4: even mild activities cannot be performed

(Note: Here, Moderate activity: regular activities including household work and office work of whatever type it may used be, mild activity: at least the activities required for oneself i.e clothing, bathing, going to washroom alone etc. independently.)

**Roukshya:**
Graded according to the cracks on skin due to dryness-
- None- no cracks- 0
- Mild – superficial cracks- 1
- Moderate- cracks without bleeding- 2
- Severe – cracks with bleeding- 3

**Keshapatan:**
Gradations assigned as follows-
- Grade 0: no hair fall
- Grade 1: hair fall once in the morning while washing/combing
- Grade 2: hair fall on every time of combing
- Grade 3: visible or considerable baldness in frontal/vertex region &/or hair loss even without combing even just by touching hair.

**Katishool:**
Katishool was assessed on the basis of oxford pain chart as described earlier.

**Sandhi shool:**
Pain in the other joints of patients was also assessed. For this again Oxford Pain Chart was used.

The assessment of Overall relief

The assessment of Overall relief was done using the VAS Scale. There is 10 cm long scale for assessment of overall relief. There is ‘0’ marking on left hand side and ‘10’ marking on right hand side. ‘0’ indicates complete relief while 10 indicate severe distress. Patients were asked to grade their severity of overall pain and allied complaints. Marking was defined accordingly in number.

```
0 __________________________________________ 10
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The reading was taken on the first and last day of the follow up i.e on Day 1 & 90.

**OBSERVATIONS AND RESULTS**

30 patients registered in the trial were followed up regularly and the data collected from this showed that Highest no of patients 14 (47%) were from age group 45-55, 17 patients (57%) were female, 24 patients (80%) were Hindus, 18 patients (60%) had secondary education, 18 patients (60%) were taking mixed diet. Among 30 patients 15 patients (50%) had disturbed sleep, 20 patients (67%) were of madhyam aakruti (neither thin nor fat), 11 patients (37%) were not addicted to anything and 16 patients (55%) were of vatapradhan pittan-ubandhi prakruti. Among 30 patients sandhishoola, katishoola and asthishoola were commonly found. Effect of drug on these parameters is shown in the figures.

**DISCUSSION**

Observations withdrawn from this work were studied, appropriate statistical tests were applied to the data and results were interpreted as follows.

**Discussion on results:**

**Effect of medicine on Subjective parameters:** The statistical assessment shows effect of medicine was extremely significant in all parameters.

- **Asthishool:** Analysis of means before and after treatment showed that patients got 55.58% relief in asthishool after treatment. 20 patients experienced 1 grade relief whereas 10 patients experienced neither relief nor increase in the symptom. Wilcoxon matched pair signed rank test showed that p value was <0.0001 i.e highly significant, proving efficacy. This treatment pacifies vata, nourishes asthi dhatu, hence shool (pain) the cardinal symptom of vata vitiation was relieved.

- **Katishool:** Analysis of means before and after treatment showed that patients experienced 51.64% relief in katishool after treatment. 3 patients got 2 grade relief which was significant, 23 patients got 1 grade relief whereas 4 patients had neither relief nor increase in the symptom. Wilcoxon matched pair signed rank test showed that p value was <0.0001 i.e highly significant, proving efficacy. ‘Kati’ is the site of vata & consists of the structures lying in the vicinity of Pakwashaya. Since basti administered in pakwashaya acts on chief site of vata, has properties to pacify vata and development of asthi, it helps in relieving Katishool of asthikshaya.

- **Sandhishool:** Analysis of means before and after treatment showed that patients experienced 52.94% relief in sandhishool after treatment. 27 patients experienced 1 grade relief whereas 3 patients experienced neither relief nor increase in the symptom. Wilcoxon matched pair signed rank test showed that p value was <0.0001 i.e highly significant, proving efficacy. Sandhishool in asthikshaya is primarily of asthi sandhis i.e joints of bones. Hence treatment helps in relieving it.

- **Roukshya, Shrama & Keshapatan:** Wilcoxon matched pair signed rank test showed that p value was highly significant for all the 3 parameters proving efficacy in all of them. Analysis of means before and after treatment showed that patients got 41.37% relief in roukshya, 33.31% relief in shrama & only 18.45% relief in keshapatan after treatment. Shrama and Roukshya occur predominantly due to vata vitiation hence as the vitiated vata decreases, both the symptoms reduce and show good relief even after 30 days of treatment. But since keshapatan is the direct consequence of asthikshaya and hair are formed along with asthi which takes 20 days, very significant improvement in this symptom with 30 days treatment is not observed.

**Effect of medicine on Objective parameter (BMD T-Score):** Statistical analysis was done by using paired t test. P value was 0.0023 i.e. highly significant and proving that BMD t score increases with 0.78% after treatment.

**Overall effect of the treatment:** assessed using Visual Analogue Scale (VAS) and considering all parameters together. Paired t test was applied which showed P <0.0001 proving highly significant effect of treatment. Patients experienced overall 31.98% relief from the treatment.

**MODE OF ACTION OF DRUG:**

According to Commentator Arundatta the substance that produces Khratwa (roughness) due to snigdha (unctuous) and shoshan (drying) properties increases asthi, as asthi is also khara by nature. But no substance is available that has both snigdha and shoshan properties. So ksheer (milk) and ghrut (ghee) which are snigdha in nature are advised to be used with the substances which are Tikta (Bitter) and possess shoshan (drying) property.

**Properties of constituents of Panchatikta gana:**

- **Rasa:** Predominant- Tikta, Associate rasa- Katu or kashaya
  - **Vipaka:** Katu ; Except guduchi (Madhur vipaka)
  - **Properties:** Ruksha, Laghu

**Combination possesses properties which are in favor of vata aggravation.**

- **Milk & Ghee:** Both are snigdha, mrudu, manda and sara.
CONCLUSION
On the basis of Observations, following conclusion can be drawn:

Panchatikta Ksheer basti is effective in the treatment of asthikshaya especially in relieving the symptoms like kati-shool, asthishool and sanshishool.

Improvement in the BMD T score is also encouraging.

Scope for future study:
Trial should be taken over large number of subjects and for longer duration.

Table 1- Bone Mineral Density (‘t’-score)

<table>
<thead>
<tr>
<th>Category</th>
<th>Bone Mineral Density (‘t’-score)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>A value of t-score within ‘1’ standard deviation of young i.e. &gt;-1.0</td>
</tr>
<tr>
<td></td>
<td>Adult reference mean, i.e. t-score &lt; -1.</td>
</tr>
<tr>
<td>Osteopenia</td>
<td>A value of t-score more than ‘1’ and less than 2.5 standard deviation below the young adult reference mean i.e. &gt;-1.0 &amp; &lt; -2.5</td>
</tr>
<tr>
<td></td>
<td>i.e. -1 &lt; t-score &lt; -2.5.</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>A value of t-score more than 2.5 standard deviation below the young adult reference mean, i.e. t-score &gt;-2.5.</td>
</tr>
</tbody>
</table>

Figure 1- EFFECT OF TREATMENT ON SUBJECTIVE PARAMETERS

Figure 2- EFFECT OF THE TREATMENT ON OBJECTIVE PARAMETERS

REFERENCE