Calcium Orotate in Osteoporosis


Abstract— Osteoporosis is disease of bones affecting both men and women, where bones become weak with age and easily prone to fractures. Menopause is an uncontrollable risk factor which makes women more susceptible to osteoporotic fractures. Variations in elemental calcium absorption from different calcium preparations has lead to a great concern over the dose and best possible calcium supplement for daily use. Hence the present study was designed to assess the efficacy and other beneficial effects of calcium orotate in comparision with calcium carbonate + Vit D3. The study was designed to be randomized double blind prospective with 80 female postmenopausal osteoporotic patients between the age group of 50-80 years. The patients were divided into two groups, one group received Calcium orotate while the other was given calcium carbonate + Vit D3. The results showed a highly significant increase in serum calcium levels in both the groups. The group on calcium orotate showed two fold increase in serum calcium levels and physical activity when compared to Calcium carbonate + Vit D3 group.

Keywords—Calcium orotate, Osteoporosis, Postmenopausal women.

I. INTRODUCTION

OSTEOPOROSIS is a common condition where bones become weak, affecting both men and women, mainly as they grow older. It is a silent condition where the bones are weak and prone to fracture. Bone is a living tissue that is in a constant state of regeneration and involving two processes – bone resorption and bone formation. With age, there occurs an imbalance in bone resorption and bone formation resulting in thinner bones with weaker structures [1].

Menopause is one of the uncontrollable risk factors for osteoporosis and osteoporotic fractures [2]-[4]. Bone resorption increases as a result of hormone deprivation in perimenopausal years. Increased bone formation occurs at menopause due to increase in bone remodelling markers. However, the increased bone formation cannot compensate for the increased resorption – an imbalance resulting in bone loss after menopause [5].

Different calcium preparations vary in the absorption of elemental calcium from them resulting in great concern in patients with osteoporosis. Calcium orotate is a calcium salt of mineral transporter i.e. orotic acid which ensures target specific delivery of calcium due to its dissociation in osteoblasts. Calcium orotate has beneficial effects on reclcification of bone metastases on cartilage tissue and also on osteoporosis [6].

The present study was designed to compare the efficacy of calcium orotate with calcium carbonate + Vit D3 in postmenopausal osteoporotic women. And also to assess the effect of the study drugs, on improving the patients’ impairment and quality of life.

II. SUBJECTS AND METHODS

It was Randomized double blind prospective study. The study was carried out at ESIC Hospital, Warangal, after obtaining permission from Institutional Ethics Committee and informed consent. The patients who declared their willingness to participate in the study after explaining the whole procedure of the study were considered for inclusion in the study.

A total of 80 female postmenopausal patients aged between 50-80 years suffering from osteoporosis were randomly selected for the study from General Medicine outpatient. The patients were subjected to undergo BMD scan using Sunlight MiniOmni S 3.1.0 Probe S/N CMC7716. The patients reported with T-value <-2.5 were included in the study.

The inclusion criteria was postmenopausal osteoporotic women, with age above 50 years and non-diabetic. Female subjects who underwent hystectomy, or diabetic were excluded from the study.

The patients were randomly divided into two groups. One group was given calcium carbonate + Vit D3, while other group received calcium orotate as supplement.

Calcium carbonate (500mg, elemental calcium 500mg) + vitamin D3 (250 IU) – once daily. Brand name: Cipcal, Mfg By: Cipla.

Calcium orotate (740mg, elemental calcium – 152.4mg) – once daily. Brand name: Cdense. Mfg By: Wanbury.

The study was carried out for duration of 2 months (September 2012 to October 2012). During this period, the baseline serum calcium of patients was recorded and calcium supplements were given. The baseline data for Oswestry Disability Index [8] was also recorded.

After two months the patients were then investigated for response to the ongoing treatment by recording their serum calcium levels. The patients were asked to fill the Oswestry Disability Index and the scores recorded.

The patients were personally interrogated for the presence of any adverse events. All the information collected from the patient was recorded in case record forms.

The patients were given counselling on the importance of compliance to the medication and were advised regarding suitable life style modifications required for a better response to the treatment. The patients were given a clear idea about the use of the medication and treatment regimen.

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The outcome measures to the ongoing treatment were increase in serum calcium levels and decrease in mean difference of Oswestry Disability Index.

### III. RESULTS

#### TABLE I
**DEMOGRAPHIC DATA**

<table>
<thead>
<tr>
<th>S.No</th>
<th>Age (years)</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>50-55</td>
<td>33</td>
</tr>
<tr>
<td>2</td>
<td>56-60</td>
<td>19</td>
</tr>
<tr>
<td>3</td>
<td>61-65</td>
<td>15</td>
</tr>
<tr>
<td>4</td>
<td>66-70</td>
<td>8</td>
</tr>
<tr>
<td>5</td>
<td>71-75</td>
<td>5</td>
</tr>
</tbody>
</table>

#### TABLE II
**EFFECT ON SERUM CALCIUM**

<table>
<thead>
<tr>
<th>S.No</th>
<th>Drug</th>
<th>Serum Calcium</th>
<th>Increase in Serum Calcium</th>
<th>% Increase</th>
<th>95% CI P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>C</td>
<td>6.79±1.79</td>
<td>1.42</td>
<td>6.22-7.36</td>
<td>7.79-8.63 &lt;0.0001</td>
</tr>
<tr>
<td>2</td>
<td>O</td>
<td>6.40±1.51</td>
<td>2.97</td>
<td>5.92-6.89</td>
<td>9.07-9.68 &lt;0.0001</td>
</tr>
</tbody>
</table>

C- Calcium carbonate + Vit D3; O- calcium orotate  
B- Baseline; A-After treatment  
CI- confidence interval (lower & upper limits)  
Values are expressed as mean±SD

#### TABLE III
**EFFECT ON DISABILITY INDEX**

<table>
<thead>
<tr>
<th>S.No</th>
<th>Drug</th>
<th>DI</th>
<th>% Decrease in DI</th>
<th>% Decrease in DI 95% CI P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>C</td>
<td>68.06±16.06</td>
<td>9.65±4.61</td>
<td>62.92-73.19 53.74-63.08 &lt;0.0001</td>
</tr>
<tr>
<td>2</td>
<td>O</td>
<td>69.85±17.89</td>
<td>26.17±15.67</td>
<td>64.13-75.58 39.58-47.79 &lt;0.0001</td>
</tr>
</tbody>
</table>

DI- Disability Index  
C- Calcium carbonate + Vit D3; O- calcium orotate  
B- Baseline; A-After treatment  
CI- confidence interval (lower & upper limits)  
Values are expressed as mean±SD

#### TABLE IV
**EFFECT ON NECK DISABILITY INDEX**

<table>
<thead>
<tr>
<th>S.No</th>
<th>Drug</th>
<th>NDI</th>
<th>% Decrease in NDI</th>
<th>% Decrease in NDI 95% CI P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>C</td>
<td>76.62±21.89</td>
<td>14.7</td>
<td>69.61-83.62 60.6-70.1 &lt;0.001</td>
</tr>
<tr>
<td>2</td>
<td>O</td>
<td>67.97±21.11</td>
<td>38.5</td>
<td>61.22-74.72 41.3-50.8 &lt;0.001</td>
</tr>
</tbody>
</table>

NDI- Neck Disability Index  
C- Calcium carbonate + Vit D3; O- calcium orotate  
B- Baseline; A-After treatment  
CI- confidence interval (lower & upper limits)  
Values are expressed as mean±SD

#### TABLE V
**EFFECT ON FUNCTIONAL STRENGTH OF CERVICAL SPINE**

<table>
<thead>
<tr>
<th>S.No</th>
<th>Drug</th>
<th>FSCS</th>
<th>% Increase in FSCS</th>
<th>% Increase in FSCS 95% CI P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>C</td>
<td>5.58±2.0</td>
<td>4.38±1.72</td>
<td>5.74-6.45 &lt;0.001</td>
</tr>
<tr>
<td>2</td>
<td>O</td>
<td>6.29±2.67</td>
<td>3.38±1.93</td>
<td>4.62-4.11 &lt;0.001</td>
</tr>
</tbody>
</table>

FSCS- Functional Strength of Cervical Spine  
C- Calcium carbonate + Vit D3; O- calcium orotate  
B- Baseline; A-After treatment  
CI- confidence interval (lower & upper limits)  
Values are expressed as mean±SD

#### TABLE VI
**CALCIUM CARBONATE + VIT D3 VS CALCIUM OROTATE**

<table>
<thead>
<tr>
<th>S.No</th>
<th>Parameters</th>
<th>Calcium carbonate + Vit D3</th>
<th>Calcium orotate</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Serum Calcium</td>
<td>1.42±1.23</td>
<td>2.97±1.14</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>2</td>
<td>Decrease in Disability Index</td>
<td>9.65±7.90</td>
<td>26.17±15.67</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>3</td>
<td>Decrease in Neck Disability Index</td>
<td>11.24±10.54</td>
<td>26.17±15.67</td>
<td>0.0003</td>
</tr>
<tr>
<td>4</td>
<td>Increase in Functional Strength of Cervical Spine</td>
<td>2.48±1.55</td>
<td>4.38±1.72</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
IV. DISCUSSION

Treatment with calcium supplements for two months showed a highly significant increase in the results of both the groups. Treatment with calcium orotate for 2 months resulted in more than two fold increase in serum calcium levels in women with post menopausal osteoporosis as compared to treatment with calcium carbonate + vit D3, which was highly significant.

The assessment parameters in Oswestry Disability Index showed a highly significant increase in the activity and symptomatic relief of osteoporotic patients. The calcium orotate group reported almost twice the improvement in assessment parameters when compared with the group on calcium carbonate + vit D3.

Regarding the comparisons of safety of calcium orotate and calcium carbonate, there were no adverse events and serious adverse events reported with any of the treatment groups in this study. Hence, calcium orotate and calcium carbonate were comparable in their safety and tolerability.

IV. CONCLUSION

In conclusion, 2 months of calcium orotate therapy in women with postmenopausal osteoporosis significantly increased serum calcium levels and reduced the symptoms of osteoporosis with no side effects. These results suggest that calcium orotate is an important therapeutic option in the treatment of women with postmenopausal osteoporosis when compared to calcium carbonate + vit D3 treatment.

REFERENCES