

## A SURVEY ON TREATMENT REGIMENS USED IN THE COMMUNITY AND A TEACHING HOSPITAL FOR OSTEOPOROSIS- A COMBINED STUDY IN NORTHERN KERALA

Kunhi Kannan<sup>1</sup>, Muhammed Musthaque<sup>2</sup>

<sup>1</sup>Associate Professor, Department of General Medicine, Kannur Medical College, Anjarakandy, Kannur, Kerala.

<sup>2</sup>Associate Professor, Department of General Medicine, Kannur Medical College, Anjarakandy, Kannur, Kerala.

### ABSTRACT

#### BACKGROUND

Osteoporosis is a common clinical condition with features of low bone mass and microarchitectural collapse of bone tissue with enhanced bone fragility and increased susceptibility to fracture. Nowadays, it is recognised as a major health problem as it leads to an increased risk of developing spontaneous and traumatic fractures. In India, osteoporotic fractures occur more commonly in both sexes and may occur at a younger age than in the western countries. Though exact prevalence of the disease is not available, nearly 36 million Indians maybe suffering from osteoporosis by 2013. At present, most drugs available in the markets decrease bone loss by inhibiting bone resorption, but the upcoming therapies may increase bone mass by directly increasing bone mass as is the case of parathyroid hormone.

The aim of the study is to conduct a clinical survey of treatment regimens used in the community and a tertiary hospital for osteoporosis.

#### MATERIALS AND METHODS

The clinical and prescription data of 276 patients were analysed in the northern part of Kerala. The diagnostic criteria used for confirmation of osteoporosis, treatment regimens used, their efficacy and side effects were observed and analysed using standard statistical methods. Patients were divided into 2 groups; group A with 116 patients attending the teaching hospital and 160 groups B patients' information obtained from physicians in the community.

#### RESULTS

Among 276 patients, 197 were females and 79 were males with a male-to-female ratio of 1:2.49. Group A showed 28.4% in the 66 to 70 years age group; group B showed 28.75% in the 66 to 70 years age group. The baseline lab investigations were normal. The DXA results in both groups showed T score <2.5 and more in 199 patients (72.10%). The overall incidence of osteoporotic fractures was observed in 63 patients (22.82%). The frequently used treatment regimen was vitamin D and calcium.

#### CONCLUSION

Osteoporosis was noted more commonly in females than in males. The commonest age group affected was 66 to 75 years. Baseline laboratory investigations are found to normal. The most preferred investigation among the physicians was Dual-Energy X-Ray Absorptiometry (DXA). The commonly used regimen was calcium and vitamin D followed by bisphosphonates. The compliance rate of all the regimens was equal. The overall patient compliance for different regimens using Chi-square calculator using (5 x 5) contingency table the Chi-square statistic was 4.3242. The p-value was 0.3639. The result was not significant at p<0.05. Comparing the end results of different regimens of treatment used in Groups A and B using Chi-square calculator using (5 x 5) contingency table the Chi-square statistic was found to be 1.0482. The p-value was 0.902. The result is not significant at p<0.05.

#### KEYWORDS

Age, Elderly, Osteoporosis, Drugs, Anti-Osteoporotic Drugs, Metabolism and Calcium.

**HOW TO CITE THIS ARTICLE:** Kannan K, Musthaque M. A survey on treatment regimens used in the community and a teaching hospital for osteoporosis- A combined study in Northern Kerala. J. Evid. Based Med. Healthc. 2017; 4(26), 1557-1563. DOI: 10.18410/jebmh/2017/304

#### BACKGROUND

Osteoporosis is recognised as a major health threat in ageing persons recently. Change in lifestyles of population

*Financial or Other, Competing Interest: None.*

*Submission 02-03-2017, Peer Review 09-03-2017,*

*Acceptance 23-03-2017, Published 29-03-2017.*

*Corresponding Author:*

*Dr. Kunhi Kannan,*

*Associate Professor, Department of General Medicine,*  
*Kannur Medical College, Anjarakandy, Kannur, Kerala.*

*E-mail: kmcprincipaloffice@gmail.com*

*DOI: 10.18410/jebmh/2017/304*



combined with ageing and increase in survival rate has resulted in steady increase in the incidence of fractures all over the World.<sup>1,2,3</sup> Primary osteoporosis is defined as a metabolic bone disease characterised by low bone mass and microarchitectural deterioration of bone tissue leading to enhanced bone fragility and increased fracture risk.<sup>4,5</sup> Osteoporosis is an underrecognised condition especially in men until the condition is at an advanced stage 1 and apart from old age more than 50% of the times the cause of male osteoporosis is secondary.<sup>6</sup> The prevalence of osteoporosis in rural Indian population has not been studied yet. We

found the prevalence in our population 32.47%.<sup>7</sup> In India, the problem of osteoporosis is as much as in throughout the world. Majority of the postmenopausal women and aged population are affected.<sup>8</sup> In osteoporosis, there is decrease in bone mass due to activation of osteoclasts, which enhances bone resorption. Postmenopausal osteoporosis is the most common primary type and is characterised by rapid bone loss in recently postmenopausal women. Therefore, knowledge of appropriate timing of peak bone mass and bone mineral density is essential if preventive measures are to be adequately taken.<sup>9</sup> Loss of bone mass itself is asymptomatic until a fracture occurs.<sup>10</sup> Treatment options with (e.g., bisphosphonate and combination with the latter, denosumab, strontium ranelate) have shown to reduce the risks of fractures of vertebrae and hip,<sup>11,12</sup> but no single drug showing superiority over the others.<sup>13</sup> In India, population is expected to increase to 1,367 million by 2020 and 1,613 million by 2050. Out of this population, 9.8% (134 million) and 19.6% (315 million) respectively will be people aged above 60 years.<sup>14</sup> This population would be at risk for osteoporosis in India in the years to come and becomes a serious problem for the economy and health. Few estimates in a study suggest that 20% of women and about 10-15% of men are osteoporotic in India.<sup>15</sup> Another study group estimate, 26 million Indians suffer from osteoporosis and this number is expected to reach 36 million by 2013.<sup>16</sup> The present study aims at describing the pattern of drugs used, the choice of active anti-osteoporotic medicines used in the Northern part of Kerala.

## MATERIALS AND METHODS

Data related to 276 patients was included in the present study. 116 patients attending the OPD of Department of Medicine, Kannur Medical College, Anjarakandy, Kannur, between February 2010 and January 2013 were grouped as group A. 160 patients were grouped as B whose data was collected through a printed questionnaire circulated among the practitioners (physicians, gynaecologists, general practitioners, orthopaedic surgeons and general surgeons) in and around Kannur District of Kerala who were treating osteoporosis patients. The questionnaire was prepared to-

1. Collect the demographic data.
2. Clinical features.
3. Diagnostic criteria used to diagnose osteoporosis.
4. Details of drugs used in the treatment of osteoporosis, their indications, duration of treatment, the prescribing pattern and their choice.

## Inclusion Criteria

1. Patients aged above 50 years both males and females who were diagnosed as suffering from osteoporosis based on clinical and lab investigations.
2. Patients with a confirmed diagnosis of osteoporosis with Dual-Energy X-Ray Absorptiometry (DXA).
3. Patient's upper age limit was not limited.

## Exclusion Criteria

1. Patients with history of fractures.
2. Patients aged below 50 years.
3. Patients with thyroid or parathyroid diseases.
4. Patients with secondary osteoporosis.

Similarly, the information of usage of prescribed active anti-osteoporotic drugs was collected from older prescriptions of elderly patients attending the Hospital Medicine OPD. A written informed consent was obtained from all the patients included in the study. For each inpatient admission, also available data included patient demographics, medications, laboratory, diagnostic and therapeutic services were obtained. All the patients were subjected to detailed physical examination and laboratory baseline investigations. The laboratory investigations included complete haemogram including haemoglobin, albumin, total protein, triglycerides, total cholesterol, corrected calcium, blood urea nitrogen, creatinine and phosphates. All the patients were subjected for ultrasound bone densitometry to assess the bone loss before starting drug therapy. For confirmation of the diagnosis of osteoporosis, Dual-Energy X-Ray Absorptiometry (DXA) was used. The World Health Organization (WHO) criteria for diagnosis of osteoporosis was used defining BMD that lies 2.5 standard deviations or more below the average value for young healthy women (a T-score of  $<-2.5$  SD). The data was analysed and was expressed as numbers and percentages. Microsoft excel version 2013 was utilised for analysis and graphical representation of data.

## OBSERVATIONS AND RESULTS

Out of total 276 patients, 197 were females and 79 were males with a male-to-female ratio of 1:2.49. Among the 160 patients whose data was collected through questionnaires, 115 were females and 45 (M:F-1:2.55) were males. Among the OPD patients of 116, females were 86 and 30 were males (M:F-1:2.86). In the present study, patients belonged to the age groups of 50 to 95 years. The incidence of osteoporosis in group A showed 29.31% in the 71 to 85 years age group, 28.4% in the 66 to 70 years age group, 22.41% in the 50 to 65 years age group and 19.82% in the 85 to 100 years age group (Table 1). The incidence of osteoporosis in males of group A is 25.86% and the age group of 71-85 years showed an incidence of 9.48% followed by 85 to 100 years (6.89%). Diabetes mellitus was observed in 27.58% of the patients, chronic lung diseases in 23.27%, cardiovascular diseases in 22.41% and vision impairment in 21.55% as the comorbid conditions (Table 1). Less common co-morbid conditions were liver diseases and G.I.T. disturbances.

| Sex ↓                       | Age Groups → | 50-65 Yrs.<br>26- (22.41%) | 66-70 Yrs.<br>33- (28.40%) | 71-85 Yrs.<br>34- (29.31%) | 85-100 Yrs.<br>23- (19.82%) |
|-----------------------------|--------------|----------------------------|----------------------------|----------------------------|-----------------------------|
| Male- 30 (25.86%)           |              | 04                         | 07                         | 11 (9.48%)                 | 08 (6.89%)                  |
| Female- 86                  |              | 22                         | 26                         | 23                         | 15                          |
| <b>Co-Morbid Conditions</b> |              |                            |                            |                            |                             |
| Cardiovascular disease- 26  |              | 06                         | 08                         | 06                         | 06                          |
| Diabetes mellitus- 32       |              | 09                         | 09                         | 06                         | 08                          |
| Hypothyroidism- 24          |              | 05                         | 06                         | 10                         | 03                          |
| Lung diseases- 27           |              | 07                         | 06                         | 07                         | 07                          |
| Renal diseases- 23          |              | 00                         | 07                         | 08                         | 08                          |
| Depression- 21              |              | 04                         | 08                         | 04                         | 05                          |
| Vision impairment- 25       |              | 09                         | 06                         | 03                         | 07                          |
| Liver diseases- 20          |              | 03                         | 04                         | 07                         | 06                          |
| G.I.T. disturbances- 23     |              | 01                         | 05                         | 09                         | 08                          |
| Degenerative arthritis- 21  |              | 07                         | 04                         | 06                         | 04                          |

**Table 1. Showing the Demographic Data and Co-Morbid Conditions of Group A (n=116)**

The incidence of osteoporosis in group B showed 26.87% in the 71 to 85 years age group, 28.75% in the 66 to 70 years age group, 20.62% in the 50 to 65 years age group and 23.75% in the 85 to 100 years age group (Table 2). The incidence of osteoporosis in males of group B is 28.12% in the age group of 71-85 years showed an incidence of 10% followed by 66 to 70 years (9.37%). Diabetes mellitus was observed in 31.87% of the patients, chronic lung diseases in 16.87%, cardiovascular diseases in 36.87% and vision impairment in 27.50% as the co-morbid conditions (Table 2). Less common co-morbid conditions were liver diseases and G.I.T. disturbances.

| Sex ↓                               | Age Groups → | 50-65 Yrs. -<br>33 (20.62%) | 66-70 Yrs. -<br>46 (28.75%) | 71-85 Yrs. -<br>43 (26.87%) | 85-100 Yrs. -<br>38 (23.75%) |
|-------------------------------------|--------------|-----------------------------|-----------------------------|-----------------------------|------------------------------|
| Male- 45                            |              | 08                          | 15                          | 16                          | 06                           |
| Female- 115                         |              | 25                          | 31                          | 27                          | 32                           |
| <b>Co-Morbid Conditions</b>         |              |                             |                             |                             |                              |
| Cardiovascular disease- 59 (36.87%) |              | 11                          | 14                          | 18                          | 16                           |
| Diabetes mellitus-51 (31.87%)       |              | 10                          | 12                          | 13                          | 16                           |
| Hypothyroidism-33                   |              | 08                          | 06                          | 12                          | 07                           |
| Lung diseases-27 (16.87%)           |              | 07                          | 06                          | 07                          | 07                           |
| Renal diseases-25                   |              | 02                          | 07                          | 08                          | 08                           |
| Depression-36                       |              | 08                          | 08                          | 09                          | 11                           |
| Vision impairment-44 (27.50%)       |              | 08                          | 10                          | 11                          | 15                           |
| Liver diseases-24                   |              | 07                          | 04                          | 07                          | 06                           |
| Degenerative arthritis- 29          |              | 03                          | 07                          | 09                          | 10                           |

**Table 2. Showing the Demographic Data and Co-Morbid Conditions of Group B (n=160)**

The mean age of patients in the group A was 71.43% and median was 76.26%; similarly in group B, the mean age was 74.10% and median was 78.40%. The incidence of females was 72.60% and males were 27.30% in group A. The incidence of females was 77.82% and males were 23.18% in group B (Table 3). In group A, among the risk factors of osteoporosis, calcium deficiency was found in 34.75%, androgen and oestrogen deficiency was found in 31.44%, lack of exercise in 32.64% and family history in 46.84%. In group B, among the risk factors of osteoporosis, calcium deficiency was found in 37.12%, androgen and oestrogen deficiency was found in 32.86%, lack of exercise in 50% and family history in 55.62% (Table 3). Other factors observed are tabulated in the Table 3.

|                                     |        | Group A | Group B |
|-------------------------------------|--------|---------|---------|
| <b>Risk Factors</b>                 |        |         |         |
|                                     | Age    |         |         |
|                                     | Mean   | 71.43   | 74.10%  |
|                                     | Median | 76.26%  | 78.40%  |
| Sex                                 | Female | 72.60%  | 77.82%  |
|                                     | Male   | 27.30%  | 23.18%  |
| Smoking                             |        | 13.44%  | 14.63%  |
| Exercise                            |        | 50.00%  | 55.62%  |
| Family history                      |        | 46.84%  | 47.60%  |
| Low body weight                     |        | 11.34%  | 12.66%  |
| Alcohol usage                       |        | 31.84%  | 33.45%  |
| Early menopause                     |        | 13.72%  | 14.63%  |
| Calcium deficiency                  |        | 34.75%  | 37.12%  |
| Poor health                         |        | 10.32%  | 10.14%  |
| Androgen or oestrogen deficiency    |        | 31.44%  | 32.86%  |
| Drugs inhibiting calcium absorption |        | 12.37%  | 14.85%  |
| Using steroids                      |        | 18.20%  | 16.45%  |

**Table 3. Showing the Risk Factors Observed in Groups A and B (n-116 and n-160)**

Laboratory investigations of group A showed haemoglobin levels ranged between 9.4 to 12.2 gms/L, albumin 3.0 to 3.8 mg/dL, triglycerides from 74.4 to 83.5 mg/dL, creatinine from 1.8 to 2.0 and cholesterol from 157.4 to 169.4 (Table 4).

| Sex ↓                                                             | Age Groups →                | 50-65 Yrs. | 66-70 Yrs. | 71-85 Yrs. | 85-100 Yrs. |
|-------------------------------------------------------------------|-----------------------------|------------|------------|------------|-------------|
|                                                                   | Male- 45                    | 08         | 15         | 16         | 06          |
|                                                                   | Female- 115                 | 25         | 31         | 27         | 32          |
|                                                                   | <b>Lab Investigations</b>   |            |            |            |             |
|                                                                   | Haemoglobin ( g/L)          | 12.2       | 10.6       | 10.8       | 09.4        |
|                                                                   | Albumin (mg/dL)             | 3.8        | 3.2        | 3.9        | 3.0         |
|                                                                   | Total protein (mg/dL)       | 5.8        | 6.0        | 5.6        | 5.2         |
|                                                                   | Triglycerides (mg/dL)       | 79.6       | 82.4       | 83.5       | 74.4        |
|                                                                   | Total cholesterol (mg/dL)   | 160.6      | 164.2      | 169.4      | 157.4       |
|                                                                   | Corrected calcium (mg/dL)   | 9.02       | 8.90       | 8.75       | 9.04        |
|                                                                   | Blood urea nitrogen (mg/dL) | 22.4       | 24.6       | 22.8       | 26.4        |
|                                                                   | Creatinine (mg/dL)          | 2.0        | 1.74       | 1.80       | 1.86        |
|                                                                   | Phosphate (mg/dL)           | 3.22       | 3.460      | 3.64       | 3.34        |
| <b>Table 4. Showing the Lab Investigations of Group A (n=116)</b> |                             |            |            |            |             |

Laboratory investigations of group B showed haemoglobin levels ranged between 10.4 and 11.8 gms/L, albumin 2.9 to 3.8 mg/dL, triglycerides from 79.2 to 84.3 mg/dL, creatinine from 1.4 to 2.0 and cholesterol from 163.2 to 176.4 (Table 5).

| Sex ↓                                                             | Age Groups →                | 50-65 Yrs. | 66-70 Yrs. | 71-85 Yrs. | 85-100 Yrs. |
|-------------------------------------------------------------------|-----------------------------|------------|------------|------------|-------------|
|                                                                   | Male                        |            |            |            |             |
|                                                                   | Female                      |            |            |            |             |
|                                                                   | <b>Lab Investigations</b>   |            |            |            |             |
|                                                                   | Haemoglobin ( g/L)          | 11.4       | 11.8       | 11.6       | 10.4        |
|                                                                   | Albumin (mg/dL)             | 3.5        | 3.8        | 3.2        | 2.9         |
|                                                                   | Total protein (mg/dL)       | 6.6        | 6.9        | 5.8        | 5.4         |
|                                                                   | Triglycerides (mg/dL)       | 81.2       | 84.3       | 80.5       | 79.2        |
|                                                                   | Total cholesterol (mg/dL)   | 163.2      | 168.4      | 174.4      | 176.4       |
|                                                                   | Corrected calcium (mg/dL)   | 9.10       | 9.12       | 9.10       | 9.14        |
|                                                                   | Blood urea nitrogen (mg/dL) | 21.4       | 20.6       | 24.8       | 27.4        |
|                                                                   | Creatinine (mg/dL)          | 1.4        | 1.54       | 1.68       | 1.76        |
|                                                                   | Phosphate (mg/dL)           | 3.42       | 3.60       | 3.84       | 3.64        |
| <b>Table 5. Showing the Lab Investigations of Group B (n=160)</b> |                             |            |            |            |             |

The Dual-Energy X-Ray Absorptiometry (DXA) results in both groups showed normal values (T score <1) in 14 (7.95%), T score <1 to 1.5 was seen in 38 (13.76%), T score 1.5 to 2 in 75 (27.17%), <2.5 and more in 199 patients (72.10%), (Table 6). The overall incidence of osteoporotic fractures was observed in 63 patients (22.82%).

| BMD Values (T score)                                                                                           | Group A-116 | Group B-160 |
|----------------------------------------------------------------------------------------------------------------|-------------|-------------|
| <1                                                                                                             | 05          | 09          |
| <1 to 1.5                                                                                                      | 22          | 16          |
| <1.5 to 2                                                                                                      | 41          | 34          |
| <2.5 and more                                                                                                  | 98          | 101         |
| Osteoporotic fracture                                                                                          | 26          | 37          |
| <b>Table 6. Showing the BMD Values (T Scores) and Osteoporotic Fractures in Group A and B (n=A-116, B-160)</b> |             |             |

Among both the groups, it was found that the treatment regimen consisting of calcium and vitamin D was used in 134 patients (86.50%), oral bisphosphonates was used in 57 patients (20.65%), IV bisphosphonates were used in 28 (10.14%), calcitonin in 10 (3.62%), teriparatide in 13 (4.71%), denosumab in 17 (6.15%), (Table 7). The response to the treatment was assessed by reduction in backache, bone pain, osteoarthritis, reduction in microfractures, improved BMD scores (T score) and psychological symptoms. The response is also assessed by patient's subjective feeling of improvement, which was observed. The overall patient compliance for different regimens using Chi-square calculator using (5 x 5) contingency table, the Chi-square statistic was 4.3242. The p-value was 0.3639. The result was not significant at p<0.05 (Table 7).

| Treatment Regimens                                                                            | Group A- 116 | Group B- 160 | Patient Compliance in Group A | Patient Compliance in Group B |
|-----------------------------------------------------------------------------------------------|--------------|--------------|-------------------------------|-------------------------------|
| Calcium and vitamin D- 134 (48.55%)                                                           | 47           | 87           | 86.50%                        | 88.24%                        |
| Oral- bisphosphonates- 57 (20.65%)                                                            | 23           | 34           | 59.58%                        | 62.12%                        |
| I.V.- Bisphosphonates- 28 (10.14%)                                                            | 16           | 12           | 79.86%                        | 76.84%                        |
| Calcitonin (intranasal)- 10 (3.62%)                                                           | 03           | 07           | 92.65%                        | 92.0%                         |
| Teriparatide- 20 (7.24%)                                                                      | 13           | 07           | 71.45%                        | 73.0%                         |
| Denosumab- 17 (6.15%)                                                                         | 08           | 09           | 76.42%                        | 74.14%                        |
| <b>Table 7. Showing the Treatment Schedules Prescribed in Group A and B (n= A-116, B-160)</b> |              |              |                               |                               |

There were no side effects observed in regimens using calcium and vitamin D. Side effects reported from patients using bisphosphonates were oesophagitis in 52.4% of group and 54.10% of group B. Similarly, other side effects noted were tabulated in Table 8.

| G.I.T. Side Effects                                                                      | Group A- 116 | Group B- 160 |
|------------------------------------------------------------------------------------------|--------------|--------------|
| Oesophagitis                                                                             | 52.4%        | 54.10%       |
| Gastric ulcer                                                                            | 9.20%        | 8.80%        |
| Gastritis                                                                                | 7.34%        | 8.0%         |
| Nausea                                                                                   | 28.43%       | 30.24%       |
| Vomiting                                                                                 | 45%          | 44.32%       |
| Dysphagia                                                                                | 16.60%       | 17.0%        |
| <b>Table 8. Showing the G.I.T. Side Effects Following Bisphosphonates Therapy (n=85)</b> |              |              |

Comparing the end results of different regimens of treatment used in Groups A and B using Chi-square calculator using (5 x 5) contingency table, the Chi-square statistic was found to be 1.0482. The p-value was 0.902. The result is not significant at  $p < 0.05$ , (Table 9).

| Observation                                                                                       | Group A- 116 | Group B- 160 |
|---------------------------------------------------------------------------------------------------|--------------|--------------|
| Reduction in backache                                                                             | 89%          | 87%          |
| Reduction in bone pain                                                                            | 77%          | 79%          |
| Reduction in osteoarthritis                                                                       | 43%          | 36%          |
| Reduction in microfractures                                                                       | 51%          | 56%          |
| Improved BMD scores                                                                               | 76%          | 81%          |
| Reduction in psychological symptoms                                                               | 39%          | 43%          |
| <b>Table 9. Showing the End Result of Regimens Used in Both the Groups A and B (n-116, n-160)</b> |              |              |

## DISCUSSION

The present study was conducted to find out the different regimens used in the treatment of osteoporosis by physicians in the community as well as physicians in a teaching hospital setup. The study also evaluated the end result of the regimens used by doctors. Out of 276 patients, 160 patient's data was based on an information obtained from a questionnaire distributed in the community to practicing physicians. The remaining data of 116 patients were obtained from prescription patterns for osteoporosis adopted by doctors in a teaching institute. The diagnostic criteria in both the groups were Dual-Energy X-Ray Absorptiometry (DEXA), clinical symptoms, signs and T score values of BMD. The diagnosis of osteoporosis in the study was not based on fragility fractures in postmenopausal women as is done by many authors because the study includes male patients also. The association between osteoporosis and fragility fractures is controversial because

fragility fracture patients are often not osteoporotic when based outcomes of care provided by the physicians to their patients.<sup>17</sup> There is no established treatment for osteoporosis in spite of advances made in medicine. When diagnosed early and treated promptly with appropriate treatment, it can only retard the disease, but cannot reverse the process.<sup>18</sup> American Association of Clinical Endocrinologists (AACE), National Osteoporosis Foundation (NOF), American College of Physicians (ACP) have laid down guidelines and recommend the methods of diagnosis and management of osteoporosis.<sup>19-21</sup> The present study was to know the treatment practices in this part of Kerala in both private practice and hospital-based practice. In western countries, the peak age of occurrence of osteoporosis is 70 to 80 years, whereas in India, the age group affected commonly is of 50-60 years.<sup>22</sup> The incidence of osteoporosis in males aged above 50 years in India is 8.5% and 53% in peri- and postmenopausal women.<sup>23</sup> Present study showed similar epidemiological parameters with female preponderance. But, the age groups involved varied from 71-85 years showing an incidence of 9.48% followed by 85 to 100 years (6.89%) in group A. In group B, it was 28.12% in the age group of 71-85 years showed an incidence of 10% followed by 66 to 70 years (9.37%). Even though, the literature reports fracture being the common clinical presentation of osteoporosis, the present study showed general symptoms like bone pain, backache to be presenting features. The overall incidence of bone fractures in the study was found to be 22.82%. Laboratory investigations such as serum albumin levels are significantly lower in patients with fragility fractures.<sup>24</sup> Serum albumin is not only an indicator in acute inflammation, but also in protein malnutrition and sarcopenia.<sup>25-27</sup> In the elderly population, protein malnutrition is associated with greater bone loss, lower BMD and muscular wasting.<sup>25,28</sup> Patients suffering from fragility fractures may also lose their normal dietary intake due to pain and disability.<sup>28</sup> The present study showed no abnormal readings in the laboratory data collected. The most favoured initial investigation among all the physicians reported in the literature is Dual-Energy X-Ray Absorptiometry (DEXA), clinical symptoms, signs and T score values of BMD. This observation goes in accordance with the guidelines that DEXA is the gold standard tool for osteoporosis diagnosis.<sup>29</sup> In the absence of a previous fracture, but if other clinical risk factors are present, a DEXA should be performed and the subject was recommended for treatment if the T-score was below -2.5 SD.<sup>30</sup> In the present study, DEXA was used in all the patients irrespective of presence or absence of fracture history. Though, there is controversy regarding the extent

of efficacy of each treatment regimen for osteoporosis in population, there is no controversy regarding the moral and legal obligation on the part of treating physician to offer or refer for treatment of osteoporosis. The current non-pharmacological methods of treatment of osteoporosis are exercise, diet (the nutrients known with certainty to be important are calcium, vitamin D and protein, phosphorus, certain trace minerals, manganese, copper and zinc), avoidance of smoking and prevention of fall play a major role in its treatment. Calcium and vitamin D supplementation are the first line strategy for the management of osteoporosis. Supplementation with calcium and vitamin D<sub>3</sub> reduced the risk of hip fractures and other non-vertebral fractures among elderly women and also a significant benefit was seen after 18 months.<sup>31</sup> For elderly patients, treatment with vitamin D may have additional benefits, because vitamin D therapy increases muscle strength and thus may reduce the possibility of fractures.<sup>32,33</sup> In the present study, 48.55% of the patients were prescribed this regimen and their compliance was more than 87% (Table 7). Bisphosphonates are used in the treatment commonly in USA. They bind to hydroxyapatite crystals and thus have a very high affinity for bone. Bisphosphonates are released from the bone matrix upon exposure to acid and enzymes secreted by an active osteoclasts.<sup>34,35</sup> Out of all bisphosphonates, zoledronic acid has the highest affinity for binding to the bone mineral matrix followed by pamidronate > alendronate > ibandronate > risedronate > etidronate > clodronate.<sup>34</sup> In the recent years, several drugs such as bisphosphonates, teriparatide and strontium ranelate are other modes of therapy; hormonal replacement therapy, selective oestrogen receptor modulators are added on.<sup>35</sup> Bisphosphonates, oestrogens and raloxifene decrease bone resorption; strontium ranelate treatment causes a mild reduction in bone resorption and a mild increase in bone formation, teriparatide increases both bone formation and bone resorption. In the present study, 20.65% of the patients were treated with bisphosphonates and their compliance was above 61%. Calcitonin acts like the endogenous form of the hormone on the calcitonin receptor on osteoclasts to decrease their activity. Out of all recombinant or synthetic calcitonin, the Salmon Calcitonin (SCT) preparation is the most widely used. It is used as nasal spray and is the most commonly used calcitonin formulation due to its convenience of administration.<sup>36</sup> In this study, calcitonin is used in 3.26% and the compliance is more than 92%. Denosumab inhibits osteoclastic activity thereby decreasing bone resorption in trabecular and cortical bone.<sup>37</sup> Denosumab is used in 6.15% and the compliance was more than 75%. A parathyroid hormone derivative and pharmacologically acts when administered intermittently at low doses teriparatide has been shown to have predominantly anabolic effects on osteoblasts. PTH initiates bone formation first and only later promotes bone formation. In the present study, teriparatide was used in 7.24% of patients and its compliance was more than 72%. The overall patient compliance for different regimens using Chi-square calculator using (5 x 5) contingency table, the Chi-square

statistic was 4.3242. The p-value was 0.3639. The result was not significant at  $p < 0.05$ . Comparing the end results of different regimens of treatment used in Groups A and B using Chi-square calculator using (5 x 5) contingency table, the Chi-square statistic was found to be 1.0482. The p-value was 0.902. The result is not significant at  $p < 0.05$ , (Table 9).

## CONCLUSION

Osteoporosis was noted more commonly in females than in males. The commonest age group affected was 66 to 75 years. Baseline laboratory investigations are found normal. The most preferred investigation among the physicians was Dual-Energy X-Ray Absorptiometry (DEXA). The commonly used regimen was calcium and vitamin D followed by bisphosphonates. The compliance rate of all the regimens was equal. The overall patient compliance for different regimens using Chi-square calculator using (5 x 5) contingency table, the chi-square statistic was 4.3242. The p-value was 0.3639. The result was not significant at  $p < 0.05$  comparing the end results of different regimens of treatment used in Groups A and B using Chi-square calculator using (5 x 5) contingency table, the Chi-square statistic was found to be 1.0482. The p-value was 0.902. The result is not significant at  $p < 0.05$ .

## REFERENCES

- [1] Burge R, Dawson-Hughes B, Solomon DH, et al. Incidence and economic burden of osteoporosis-related fractures in the United States. *J Bone Miner Res* 2007;22(3):465-475.
- [2] Cummings SR, Kelsey JL, Nevitt MC, et al. Epidemiology of osteoporosis and osteoporotic fractures. *Epidemiol Rev* 1985;7(1):178-208.
- [3] Feldstein AC, Weycker D, Nichols GA, et al. Effectiveness of bisphosphonate therapy in a community setting. *Bone* 2009;44(1):153-159.
- [4] Consensus Development Conference V, 1993. Diagnosis, prophylaxis, and treatment of osteoporosis. *Am J Med* 1994;90:646-650.
- [5] Ström O, Borgström F, Zethraeus N, et al. Long-term cost and effect on quality of life of osteoporosis-related fractures in Sweden. *Acta Orthop* 2008;79(2):269-280.
- [6] Sawka AM, Adachi JD, Papaioannou A, et al. Are there differences between men and women prescribed bisphosphonate therapy in Canadian subspecialty osteoporosis practices? *J Rheumatol* 2004;31(10):1993-1995.
- [7] Nikose S, Singh P, Khan S, et al. Prevalence of osteoporosis in female population in rural central India. *J Women's Health Care* 2015;4:262.
- [8] Ott SM. Attainment of peak bone mass. *J Clin Endocrinol Metab* 1990;71(5):1082A-1082C.
- [9] Rico H. Bone mass peak and incidence of osteoporosis and the Spanish Civil War. *Calcif Tissue Int* 1992;50(2):104.
- [10] Silverman SL, Schousboe JT, Gold DT. Oral bisphosphonate compliance and persistence: a matter of choice? *Osteoporos Int* 2011;22(1):21-26.

- [11] Delmas PD. Treatment of postmenopausal osteoporosis. *Lancet* 2002;359(9322):2018-2026.
- [12] Body JJ, Bergmann P, Boonen S, et al. Evidence-based guidelines for the pharmacological treatment of postmenopausal osteoporosis: a consensus document by the Belgian bone club. *Osteoporos Int* 2010;21(10):1657-1680.
- [13] MacLean C, Newberry S, Maglione M, et al. Systematic review: comparative effectiveness of treatments to prevent fractures in men and women with low bone density or osteoporosis. *Ann Intern Med* 2008;148(3):197-213.
- [14] World population prospects: the 2008 revision population database. United Nations Population Division 2010. <http://esa.un.org/unpp>.
- [15] Malhotra N, Mithal A. Osteoporosis in Indians. *Indian J Med Res* 2008;127(3):263-268.
- [16] The Asian audit epidemiology, costs and burden of osteoporosis in Asia 2009. [http://www.iofbonehealth.org/download/osteofound/filemanager/publications/pdf/Asian-audit-09/2009-Asian\\_Audit.pdf](http://www.iofbonehealth.org/download/osteofound/filemanager/publications/pdf/Asian-audit-09/2009-Asian_Audit.pdf), 2010.
- [17] Chen YT, Peng LN, Liu CL, et al. Orthogeriatrics in taiwan: overview and experiences. *J Clinical Gerontology Geriatrics* 2011;2(3):66-70.
- [18] Singh H, Goyal M, Singh J. Osteoporosis: current management guidelines. *Indian Journal of Clinical Practice* 2013;23(12):842-850.
- [19] Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the diagnosis and treatment of postmenopausal osteoporosis. *Endocr Pract* 2010;16(Suppl3):1-37.
- [20] National osteoporosis foundation. Clinician's guide to prevention and treatment of osteoporosis. <http://nof.org/files/nof/public/content/file/2610/upload/895.pdf>.
- [21] Qaseem A, Snow V, Shekelle P, et al. Pharmacologic treatment of low bone density or osteoporosis to prevent fractures: a clinical practice guideline from the American College of Physicians. *Ann Intern Med* 2008;149(6):404-415.
- [22] Europe guidelines. <http://www.iofbonehealth.org/europe-guidelines>.
- [23] Jhaveri S, Upashani T, Bhadauria J, et al. Current clinical practice scenario of osteoporosis management in India. *Journal of Clinical and Diagnostic Research* 2015;9(10):RC4-8.
- [24] Chen LY, Liu CL, Peng LN, et al. Associative factors of existing fragility fractures among elderly medical inpatients: a hospital-based study. *Journal of Clinical Gerontology & Geriatrics* 2012;3(3):94-96.
- [25] Petersen HH, Nielsen JP, Heegaard PM. Application of acute phase protein measurements in veterinary clinical chemistry. *Vet Res* 2004;35(2):163-187.
- [26] Soeters PB, Schols AM. Advances in understanding and assessing malnutrition. *Curr Opin Clin Nutr Metab Care* 2009;12(5):487-494.
- [27] Bourdel-Marchasson I, Laksir H, Puget E. Interpreting routine biochemistry in those aged over 65 years: a time for change. *Maturitas* 2010;66(1):39-45.
- [28] Coin A, Perissinotto E, Enzi G, et al. Predictors of low bone mineral density in the elderly: the role of dietary intake, nutritional status and sarcopenia. *Eur J Clin Nutr* 2008;62(6):802-809.
- [29] Hannan MT, Felson DT, Dawson-Hughes B, et al. Risk factors for longitudinal bone loss in elderly men and women: the Framingham osteoporosis study. *J Bone Miner Res* 2000;15(4):710-720.
- [30] Royal College of Physicians. Clinical guidelines for the prevention and treatment of osteoporosis. London, UK: RCP 1999.
- [31] Chapuy MC, Arlot ME, Duboeuf F, et al. Vitamin D3 and calcium to prevent hip fractures in the elderly women. *N Engl J Med* 1992;327(23):1637-1642.
- [32] Bischoff HA, Stahelin HB, Dick W, et al. Effects of vitamin D and calcium supplementation on falls: a randomized controlled trial. *J Bone Miner Res* 2003;18(2):343-351.
- [33] Trivedi DP, Doll R, Khaw KT. Effect of four monthly oral vitamin D3 (cholecalciferol) supplementation on fractures and mortality in men and women living in the community: randomised double-blind controlled trial. *BMJ* 2003;326:469.
- [34] Drake MT, Clarke BL, Khosla S. Bisphosphonates: mechanism of action and role in clinical practice. *Mayo Clin Proc* 2008;89(3):1032-1045.
- [35] Watts NB, Diab DL. Long-term use of bisphosphonates in osteoporosis. *J Clin Endocrinol Metab* 2010;95(4):1555-1565.
- [36] Kaufman JM, Orwoll E, Goemaere S, et al. Teriparatide effects on vertebral fractures and bone mineral density in men with osteoporosis: treatment and discontinuation of therapy. *Osteoporos Int* 2005;16:510-516.
- [37] Chesnut CH, Azria M, Silverman S, et al. Salmon calcitonin: a review of current and future therapeutic indications. *Osteoporos Int* 2008;19(4):479-491.