CHAPTER 5
SUMMARY AND CONCLUSIONS

The altering fashion in age composition of the population over time is way faster in developing countries and in India the size of the elderly population has just burst out! With rising numbers of elderly people, osteoporosis has left its foot print remarkably on the health and quality of life. Elderly suffering from this serious yet mostly preventable damage and the allied severe pain, bone fracture, long-term disability etc. can be treated promisingly by Ca and vitamin D supplementation. In preview of the recent evidences gathered, daily weight bearing exercise coupled with oral Ca ad vitamin D also is holding up to be a promising and potentially beneficial to treat poor bone health. Hence, the present study was undertaken as **"An investigation into bone mass density and it's correlation with calcium and vitamin D supplementation to the geriatric population of urban Vadodara: Evaluation of dietary intake and impact of exercise on bone health".** The study was then divided into two phases with the following objectives:

Phase I: Assessment of BMD, socioeconomic status, anthropometric parameters, nutritional status, life style, health profile of the geriatric population of urban Vadodara.

Phase II: Intervention and evaluating the efficacy of different doses of calcium and vitamin D with or without exercise on bone health of elderly males and females.

The results and the major highlights of both the phases under this study have been summarized as follows:

5.1 PHASE I

This formative phase was conducted undertaking 1056 elderly (≥60 years) subjects in the study. Subjects were enrolled from different parts of urban Vadodara by determining their BMD using an ultrasound based BMD machine. Besides, general information, anthropometric measurements, physical activities,

dietary profile, morbidity profile, biophysical profile of the subjects were gathered by one-to-one interview and direct measurements. Biochemical parameters like hemoglobin, serum Ca and vitamin D were assessed from the blood sample collected from the subjects.

Salient features of phase I

5.1.1 The subjects

- A total of 1056 subjects with a mean age of 65.3±6.6 years were enrolled in the study; that comprised 419 (39.7%) males (67.7±7.1 years) and 637 (60.32%) females (63.7±5.6 years).
- Number of young elderly included in the study was (60-69 years) was 809 (76.6%) [270 males (33.4%) and 539 females (66.62%)], old elderly (70-70 years) was 206 (19.5%) [121 males (58.73%) and 85 females (41.3%)], and oldest elderly (80 and more years) was 41 (3.9%) [28 males (68.3%) and 13 females (31.7%)].
- Mean age of young elderly was 62.3 ± 3.32, old elderly was 73.5 ± 2.8 years and oldest elderly was 83.2 ± 3.3 years.

5.1.2 Assessment of bone health amongst elderly

- Male subjects had a mean BMD T- score of -1.8±0.88 and female subjects had a mean BMD T – score of - 2.4±0.86.
- BMD test on the baseline population (N=1056) depicted a prevalence of osteopenia among 59.42% males and 47.6% females (total 52.3%); osteoporosis among 23.2% males and 47.6% females (total 37.9%), and normal BMD only among 17.42% males and 4.9% females (total 9.84%).
- Osteoporosis was prevalent among 37.08% subjects in young elderly, 40.78% in old elderly and 39.02% in oldest elderly (P- value 0.01*)
- Magnitude of osteoporosis significantly increased with age and prominently amongst females i.e. 45.3% females (20.74% males) in young elderly group (p-<0.001), 58.82% females (28.1% males) in old elderly group (p-<0.001), and 69.23% females 25% males in oldest elderly group (p-<0.05).

- An insignificant difference in BMD T- scores of the three age groups was observed.
- Age and gender combined together apparently didn't a significant decrease mean BMD of males with advancing age but females did.

5.1.3 Association of BMD with other parameters

- Data regarding the association of BMD with the baseline characteristics of the study population showed that osteopenia and osteoporosis was significantly less prevalent among the elderly who were working (p - <0.05), hence a positive association between active life and bone health was noted.
- Mean per capita income (p - <0.01) and low socioeconomic status (p - <0.01) were also found to be associated with poor bone health.

5.1.4 Activity pattern of the subjects

- Data regarding the physical activity showed that the mean time spent after exercise and yoga was significantly less among the subjects with osteopenia (p - <0.05) and followed by osteoporosis (p - <0.01) and normal BMD.
- No other activities and addiction or habits such as smoking, alcohol consumption etc. evidenced any association with BMD.
- Male subjects comparatively contributed significantly more time behind yoga and exercises, however, with advancing age it was found to be reduced. Similar trend was found in case of total time spent actively**.**

5.1.5 Anthropometric measurements of the subjects

- Mean height of the subjects with normal BMD was significantly more compared to osteopenia, followed by osteoporosis (p - <0.001). Thus, indicated a positive association between short stature and poor BMD.
- Mean hip circumference was found to be high among the subjects with poor BMD.
- Number of subjects falling under at risk category of WHR was significantly higher amongst osteopenic subjects followed by osteoporotic subjects.
- However, other anthropometric parameters did not show any significant association with BMD.

- Males possessed all the baseline anthropometric measurements significantly higher than females. Age wise classification illustrated that the weight and BMI was significant reducing with advancement in age.
- Obesity and overweight were predominantly prevalent among 66.01% and 16.56% young elderly.
- In total 64.86% subjects were at risk of having central obesity and high WHR was significantly more prevalent among men i.e. 77.57% compared to women 56.51% (p - <0.001).
- 73.17% subjects in oldest elderly group were at risk category of WHR

5.1.6 Knowledge osteoporosis, calcium and vitamin D

- Percentage of subjects aware of calcium as an important nutrient for bone health was significantly high among the subjects with normal BMD.

5.1.7 Morbidity profile of the subjects

- Data on chronic diseases showed 60% males had diabetes.
- Of all chronic illnesses, problems with central nervous system were found to be more prevalent (significant) among 11.96% osteopenic subjects and 18.75% osteoporotic subjects
- Chronic diseases such as oral problems (p-<0.001), Gastric problems (p-<0.001), locomotor problems (p-<0.001) and CVDs (p-<0.05) were significantly more prevalent among females.
- Chronic diseases such as oral problems (p-<0.05), respiratory problems (p-<0.01), CVDs (p-<0.001) and CNS problems (p-<0.01) were significantly more prevalent among old elderly subjects.
- 23.2% experienced at least one fracture, and number of males experienced fractures significantly more (p - <0.01); and the most common site reported was wrist.

5.1.8 Biophysical profile of the subjects

- Mean systolic BP of the female population was 130.3±15.8 and the diastolic BP was 83.9±10.9; keeping the males with the significantly (p–<0.01) high SBP (86.1±10.6) and DBP (130.01±13.1).

- In total only 14.4% subjects had normal systolic BP and a high percentage of subjects i.e. 58.61% were laying in the systolic pre-hypertension stage.
- Age-wise classified data showed systolic pre-hypertension was prevalent among 57.6% young elderly subjects, 60.19% in old elder elderly subjects and 70.73% in oldest elderly subjects.
- Diastolic pre-hypertension was prevalent among 36.22% young elderly subjects, 30.58% in old elderly subjects and 34.15% in oldest elderly subjects.

5.1.9 Dietary profile of the subjects

- Observations drawn from the data were an insignificant association between nutrient intake and poor BMD, yet β carotene showed a significantly less intake among the osteopenic and osteoporotic subjects.
- 99.04% males and 97.82% females were lacto-vegetarian.
- Mean nutrient intake of the subjects distributed in three BMD groups showed no significant difference; however, β carotene showed a significantly less mean intake among the osteopenic and osteoporotic subjects.
- Protein, fat, calcium and vitamin C intake appeared to be significantly high amongst females yet iron intake was significantly high (p - <0.001) among males.
- Age group-wise classification made an observation: mean energy, protein and iron intake was significant different amongst old elderly and oldest elderly groups.
- Only 30.31% males and 37.51% females could show a consumption of 76-100% RDA of calorie; and 39.14% males and 58.6% females could show a consumption of 76-100% RDA of Protein
- Scenario of Ca intake was extremely poor! Only 33.7% males and 49.3% females could show a consumption of 51- 75% RDA of Ca Same percentage of RDA of iron and vitamin C was met by <10% and around 20% subjects.
- Fat intake was observed very high among both the genders; however, number of females was significantly more in high fat intake category.

- Neither the gender nor age and subjects belonged to different BMD category showed difference in frequency of consumption of various food groups, except other vegetables and readymade items. Consumption of such products got reduced with age.

Hence, the conclusion drawn from this phase of the study that magnitude of osteoporosis was influenced by gender, age and physical activity. Male subjects intend to have better BMD T-score and apparently did not show any significant decrease in mean BMD with age, whereas females showed. Prevalence of osteoporosis was significantly higher among females and increased with age. Lack of exercise, less active life style, low socioeconomic status, low per capita income, less knowledge of osteoporosis and related nutritional care, osteoporotic, inadequate calcium intake coupled with high fat intake etc. accounted for general risk factors of osteoporosis.

5.2 PHASE II

In this phase of study 222 elderly males and females were purposefully selected and divided in four small groups i.e. A = 63, B = 59, C_1 = 50 and C_2 = 50. Group A and B received a low dose and a high dose of oral Ca and vitamin D_3 for 6 months. Whereas, group C_1 and C_2 received a low dose and with daily weight bearing exercises to perform and a low dose alone for 3 months. Herein this phase biochemical parameters assessed were hemoglobin, serum vitamin D and Ca. BMD and physical endurance test were also examined to identify the impact of supplementation. Prior to the intervention a mega dose of vitamin D_3 was supplemented to all four groups.

Salient features of phase II

5.2.1 BMD and biochemical profile of the elderly subjects

- Subjects in all four groups showed a significant increase in mean BMD, serum Ca and vitamin D.

- Group B achieved the uppermost significant decreased in mean BMD T-score (-0.97 ± 0.44) compared to group A (-1.20 ± 0.72).
- Moreover, after the intervention group B bagged the achievement of utmost significant increase of both mean serum Ca (10.21 ± 0.48 mg/dl) and vitamin D (42.73 ± 8.99 ng/ml) compared to group A (10.06 ± 0.55 mg/dl) and (35.90 ± 8.94 ng/ml), however, both pre and post serum Ca were in normal range. Post serum Ca did not show any difference in between the groups.
- Group C_1 was efficiently capable of reducing the mean BMD (pre: -2.39 ± 0.49, post: -1.86 ± 0.62) more compared to group C_2 (pre: -2.42 ± 0.55, post: -2.13 ± 0.61).
- Group C_1 attained a significant increase in both mean serum Ca (0.29 ± 0.44 mg/dl) and vitamin D (14.86 ± 7.89 ng/ml) compared to group C_2 (Ca: 0.20 ± 0.36 mg/dl and vitamin D: 9.41 ± 13.53 ng/ml).
- In group A 50.79% subjects shifted to normal BMD category and 33.34% moved out of the osteoporotic category. In group B, 54.24% subjects achieved normal BMD and 40.68% moved out of osteoporotic category. In group C_1, 38% osteoporotic subjects shifted to osteopenic and normal category. In group C_2, only 6% subjects could achieve normal BMD and 8% osteoporotic subjects shifted to osteopenic and normal category.
- After the intervention 74.60% and 25.4% subjects in group A, 89.83% and 10.17% in group B, 78% and 12% in group C_1 and 26% and 32% in group C_2 attained normal and insufficiency levels of serum vitamin D.
- Female participants achieved higher change (post - pre) in mean BMD in all four groups; however it was significant in group A (p - <0.01) and B (p - <0.01). Besides, no significant dissimilarity was detected in mean BMD when the male participants in group A and B, C1 and C2 were compared with each other and female participants in group A and B, C1 and C2 were compared with each other in both pre and post interventional stage.
- After the intervention, shift of 50% females in group A, 56.67% in group B, 56.67% in group C_1 from osteoporotic category to normal and osteopenia category was noticed compared to the shift of 19.35% males in group A, 24% in group B and 40% in group C_1. The shift evidenced a high

percentage of female subjects compared to males responded efficiently to the supplementation of oral Ca and vitamin D.

- Change in mean BMD T-score was not found to be different in between the three age groups. Besides, no significant dissimilarity was detected in mean BMD when the young elderly participants in group A and B were compared with each other and the same was observed in case of other two groups.
- After the intervention in group A 54.35% young elderly shifted to normal BMD category and 21.74% moved out of osteopenia category. Whereas, in group A only 41.18% old elderly shifted to normal category. Similarly, 53.06% young elderly and 50% old elderly in group B achieved normal BMD.
- The post interventional serum vitamin D level was elevated significantly in all four groups. Moreover, females showed significantly high serum vitamin D level compared to males in group A, C1 and C2. However, females in between the groups showed no significant difference in post interventional serum vitamin D.
- In group A 84.38% females achieved normal serum vitamin D level compared to 64.52% males. Likewise, in group B 96.76% females compared to 82.76% males, in group C_1 95% females compared to 66.67% males and in group C_2 45% females compared to 13.33% males achieved normal serum vitamin D level.
- Gender-wise difference in mean hemoglobin level was existing in both pre and post interventional phase, however, after the intervention no significant change was noted in hemoglobin level of male and female subjects (except group C2).
- After the intervention young elderly subjects in group B compared to the young elderly in group A could improve vitamin D level more significantly (p - <0.01).
- Young elderly shared 76.09% subjects with post interventional normal serum vitamin D level in group A, 91.84% in group B, 80.95% in group C_1 and 30.56% in group C2, respectively. Whereas, old elderly shared subjects with post interventional normal serum vitamin D level as 70.59% in group A, 80% in group B, 62.50% in group C_1 and only 14.29% in group C_2.

- Hemoglobin level could not show any significant association with age in any intervention group.

5.2.2 General information about the subjects

- Insignificant distinction was found in mean age, number of male and female subjects and other general parameters in all four intervention groups. This indicated that all the subjects in four different intervention groups had a totally similar background before the intervention was started.

5.2.3 Profile of daily activities of the subjects

- No significant disparity neither at the baseline nor after the trial was found in mean time contributed to various everyday routine activities by the subjects in all four intervention groups. Thus, the scope of getting the result of intervention influenced by different levels of physical activities was apparently minimized.

5.2.4 Habits and lifestyle profile of the subjects

- Both prior to the trial and after the trial no significant deviation in number of subjects having similar habits and life style was detected in four intervention groups.

5.2.5 Anthropometric profile of the subjects

- Anthropometric parameters showed an insignificant discrepancy among the groups both at the baseline and after the intervention. Thus, anthropometric parameters couldn't get the chance to interfere with the effectiveness of different interventions neither at the baseline nor during the intervention.

5.2.6 Nutrient intake of the subjects

- Subjects in all four intervention groups consumed significantly indifferent quantity of macro nutrients and micro nutrients. Thus, the impact of the four different interventions was independent of any interference of the nutrient intake at both the time points i.e. baseline and after the intervention.

5.2.7 Biophysical profile of the subjects

- Systolic and diastolic blood pressure of the subjects showed no significant discrepancy when group A was compared to group B, C_1 to C_2 both at the beginning and after the intervention.

5.2.8 Physical endurance test scores of the subjects.

- A significant raise in the mean score of all the endurance performance in both males and females was noticed; except the task rise from chair performed by females. Gender-wise evaluation of post interventional mean scores illustrated that supplementation coupled with exercise amplified the mean scores of grip strength ($p - <0.01$) and walking speed ($p - <0.05$) significantly in male subjects.
- Age-wise comparison revealed no considerable deviation between young elderly and old elderly age groups in endurance test scores.

As observed from the above findings it can be concluded that the interventional outcome was independent of any other influence such as baseline parameters, anthropometric parameters, dietary intake, biophysical parameters and physical activity among all the groups. High dose, independent of gender and age achieved the upmost significant decreased in mean BMD T-scores and increase in serum vitamin. A low daily dose of Ca and vitamin D coupled with weight bearing exercise for a longer period of time can be a choice if compliance is taken care of; and low dose for shorter tenure is not as efficient as the other two doses to improve serum vitamin D level of elderly. As far as gender and age is considered male subjects showed a significant increase in mean grip strength and walking speed scores; and young elderly subjects responded more efficiently to the high daily dose of Ca and vitamin D.

MAJOR CONCLUSIONS

- Observation was made that osteoporosis followed a trend of having a high prevalence especially among elderly females and osteopenia among males.

- Daily activities, nutrient intake, lifestyle and habits, anthropometric parameters (except height), morbidity profile and hemoglobin level could not show significant association with BMD of the chosen subjects, however physical activity did.

- Interventional outcome showed that high dose of Ca and vitamin D_3 coupled with mega dose of vitamin D_3, is recommended if a quick treatment is required and if constrictions for exercise are there. Whereas, a low dose coupled with weight bearing exercises is recommended for a long term therapy. However, in both the cases an initial mega dose of vitamin D is recommended.