CHAPTER 4

RESULTS AND DISCUSSION

The results of the present study entitled **"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"** are presented and discussed in this chapter. The results are presented into two main phases according to the objectives of the study.

Phase I: To assess the socioeconomic status, anthropometric parameters, nutritional status, life style, health profile, and to determine the bone mass density, prevalence of osteopenia and osteoporosis among 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.

Phase I: To assess the magnitude of osteoporosis and its association with the socioeconomic status, life style, anthropometric parameters, nutritional status, health profile and biophysical profile of the geriatric population of urban Vadodara.

India has witnessed a steady and progressive rise in the number of elderly population (aged 60 years or above) over the last decade. This trend of ageing is bringing a crisis in socio-economic status (SES), nutrition and health of elderly population. If we look at the health aspect of the rapidly growing elderly population, physical changes are one of the prime changes that infested as musculoskeletal, dental, digestive, visual and auditory problems etc. Among all the musculoskeletal diseases osteoporosis is the one which develops silently and can wreak havoc if not diagnosed on time and treated for. Evidences indicated that osteoporosis is a leading cause of morbidity affecting elderly populations of both the sexes in most part of the world. Several factors attribute to an increased susceptibility to osteoporosis, for example lower peak bone mass, loss of ovarian function, and reduced estrogen synthesis following menopause, socio economic status (SES), malnutrition, smoking, alcohol, sedentary life style etc.

Hence, continuing with this as a background, the present phase of the study was commenced to identify the prevalence of osteoporosis among the selected group of elderly subjects residing in urban Vadodara. This phase also will deal with the other basic information such as SES, nutrition and health profile, life style profile, anthropometric profile, biophysical profile etc. about the study population and their association with the current bone health status if any.

In favour of attaining the set objectives, a study sample of 1056 was enrolled from hospitals, senior citizen association, hospitals, clinics, haveli, temples, physiotherapy centre, women's club, rotary club, society community halls etc. located in five zones of urban Vadodara city. The detailed methodology of the aforementioned parameters has been explained in the materials and methods chapter. In order to present the data subjects were classified in three ways, i.e. BMD category-wise, gender-wise and age group-wise. Results have been shown under these three classifications. The results falling under this phase are presented under the following sub sections:

Section 4.1.1: Gender and age of the elderly subjects

Section 4.1.2: General characteristics of the subjects

Section 4.1.3: Assessment of bone health amongst elderly

Section 4.1.4 Association of BMD with other parameters

Section 4.1.5 Activity pattern of the subjects

Section 4.1.6 Anthropometric measurements of the subjects

Section 4.1.7 Dietary profile of the subjects

Section 4.1.8 Knowledge osteoporosis, calcium and vitamin D

Section 4.1.9 Morbidity profile of the subjects

Section 4.1.10 Biophysical profile of the subjects

4.1.1: Gender and age of the elderly subjects

Subjects were screened according to their age and gender and depicted in table 4.1.1. A total of 1056 subjects with a mean age of 65.3±3.6 years were enrolled in the study; that comprised 419 (39.7%) males (67.7±7.1 years) and 637 (60.32%) females (63.7±2.6 years). The subjects were further segregated in three age groups i.e. young elderly (60-69 years), old elderly (70-70 years) and oldest elderly (80 and more years). Young elderly accounted to be 809 (76.6%); that included 270 males (33.4%) and 539 females (66.62%). Old elderly accounted to be 206 (19.5%) with a mean age of 73.5 ± 2.8 years; that comprised 121 males (58.73%) and 85 females (41.3%). Oldest elderly accounted to be 41 (3.9%) with a mean age of 83.2 ± 3.3 years; that comprised 28 males (68.3%) and 13 females (31.7%). In a similar pattern Transgenerational.org (2009) had described the old age in three sub populations commonly referred as the young old (65-74 years), the old (74-84 years) and the oldest old (85+ years).

Table 4.1.1: Assessment of gender and age of the elderly subjects

Parameters	Age groups						Male	Female	Total
	60-69 years (809)		70-79 years (206)		≥80 years (41)				
	Male	Female	Male	Female	Male	Female			
No/%	270 (33.4)	539 (66.62)	121 (58.73)	85 (41.3)	28 (68.3)	13 (31.7)	419 (39.7)	637 (60.32)	1056 (100)
Mean age	62.3 ± 3.32 [a]		73.5 ± 2.8		83.2 ± 3.3		-	-	-
Mean age	63.2±3.2	61.8±3.3	73.9±2.9	72.9±2.6	83.6±3.7	82.5±2.2	67.7±7.1	63.7±2.6	65.3±3.6

Figures in parenthesis denote percentage of subjects, a – mean ± SD

4.1.2: General characteristics of the subjects

General characteristics included data regarding the marital status, religion, education, occupation, type of family, SES, income and care givers etc. Those parameters are presented in percentages.

Socio-demographic data of the subjects revealed that 365 (87.11%) males and 522 (81.94%) females were married and majority 1042 (98.7%) were Hindus. India is a country where living in a joint family is preferred traditionally. But with the changing values and life styles living in a nuclear family is the current trend. Living arrangement has a definite correlation with overall health of individual. More than half of the subjects 57.8% were living in nuclear family. Education is one of the most effective paths to have knowledge of health, nutrition, diseases and care. Among the study population 95.5 % were literate. More than half of the subjects was house bound, especially the females i.e. 498 (78.2%). A very tiny chunk of males i.e. 16.22% were engaged in some kind of jobs. Around 29.2% subjects had a family income of 10000 Rs. Per month. Overall socio economic status identified 67.34% subjects belonged to low income group. Care givers have got to play a vital role in health care of the elderly. A Health condition of elderly partially explains where they stay and the kind of health and nutritional care they receive. Subjects of the current study showed that 38.63% subjects received self-care and 30.01% received care from their spouse (Table 4.1.2.1).

Table 4.1.2.1: General characteristics of the baseline subjects

Parameters	Male (419)	Female (637)	Total (1056)
Marital status			
Married	365 (87.11)	522 (81.94)	887 (84)
Unmarried	4 (1)	11 (1.72)	15 (1.42)
Widow	00 (0.00)	99 (15.54)	101 (9.6)
Widower	50 (11.93)	00 (00)	48 (4.54)
Divorced	00 (00)	5 (0.8)	5 (0.5)
Religion			
Hindu	416 (99.3)	626 (98.3)	1042 (98.7)
Muslim	1 (0.23)	3 (0.5)	4 (0.4)

Sikh and others	(2 0.5)	8 (1.3)	10 (0.94)
Type of family			
Nuclear	243 (58)	367 (57.61)	610 (57.8)
Joint	163 (38.90)	252 (39.6)	415 (39.3)
Extended	13 (3.10)	18 (2.82)	31 (2.93)
Education			
Illiterate	21 (5.01)	25 (3.92)	47 (4.5)
Primary school	38 (9.1)	110 (17.3)	148 (14.01)
Middle school	77 (18.4)	172 (27)	249 (23.6)
High school	65 (15.51)	76 (11.93)	141 (13.4)
Graduation	171 (40.81)	186 (29.2)	357 (33.8)
Post graduation	46 (11)	68 (10.7)	114 (10.8)
Occupation			
House bound	31 (7.4)	498 (78.2)	529 (50.1)
Retired	222 (53)	90 (14.12)	312 (29.54)
Self employed	22 (5.3)	38 (6)	60 (5.7)
Service	68 (16.22)	11 (1.72)	79 (7.5)
Unemployed	76 (18.13)	00 (00)	76 (7.2)
Per capita income			
0 - 5000	208 (49.64)	455 (71.41)	640 (60.60)
>5000 – 10000	153 (36.51)	155 (24.33)	308 (29.2)
>10000	58 (13.84)	27 (4.23)	108 (10.22)
Socio economic status			
LIG	212 (50.6)	429 (67.34)	641 (60.7)
MIG	147 (35.1)	165 (26)	312 (19.54)
HIG	60 (14.31)	43 (6.8)	103 (9.8)
Care giver of the subjects			
Self	138 (32.93)	270 (42.4)	408 (38.63)
Spouse	124 (29.6)	193 (30.3)	317 (30.01)
Family	136 (32.5)	150 (23.54)	286 (27.1)
Institution	21 (5.01)	24 (3.8)	45 (4.3)

Figures in parenthesis denote percentage of subjects

4.1.3: Assessment of bone health status of the subjects

In this section prevalence of osteoporosis in total study population was mapped. Magnitude of poor BMD in both the genders and age groups was also assessed in this section.

With regard to the bone health of the elderly subjects BMD T- score revealed that the overall mean BMD was -2.14±0.91 and that apparently comes under osteopenia category (Table 4.1.3.1). Mean BMD T- score of males was -1.8±0.88 and female was -2.4±0.86, respectively. The BMD T- scores of males and females fall under the osteopenic category, however, male subjects had a significantly high baseline BMD T-scores (p – value <0.001). Thus, the inference can be made here that males intend to have better BMD T-score compared to the females of the same age. Similar evidence has been documented by Riggs BL *et. al*. (2008). The authors measured the trabecular and cortical volumetric bone mass density (vBMD) of 553 women by QCT annually for up to 3 years and documented an annual loss of −0.38% vBMD at distal radius trabecular site and −0.15% at Cortical Lumbar spine site.

Table 4.1.3.1: Bone health status of the subjects detected by Mean BMD

Parameter	Male (419)	Female (637)	Total (1056)	t - value
Mean BMD	-1.8±0.88	-2.4±0.86	-2.14±0.91	9.87 ***

Student t test, * Significant at <0.001**

Table 4.1.3.2 displays the BMD T- scores corresponding to the age group of the subjects. Males in all age groups showing significantly low BMD T-scores than females indicated better bone health. An insignificant difference in BMD T-scores of the three age groups was observed. However, the means showed a tendency of increasing BMD T- score with age. Age-wise demarcation depicted an insignificant deviation in mean BMD of male subjects in young old, older old and oldest old age groups. Contrasting males, females showed a clear better mean BMD among young elderly compared to the older elderly (p – <0.05) and young elderly with oldest elderly (p – <0.01). So, the inference derived here is age apparently didn’t show a significant decrease in mean BMD of male participants but of females. To show a similar trend in bone health of females a study done by Kuchuk NO *et. al.* (2009) is just right to cite here. The study reported a BMD T-score of postmenopausal women (N = 7441) at the femoral neck or lumbar spine as -22.5 with one to five mild or moderate vertebral fractures (multicentre study, subjects participated from 29 countries in North America, South America, Europe, Asia, Africa, Australia).

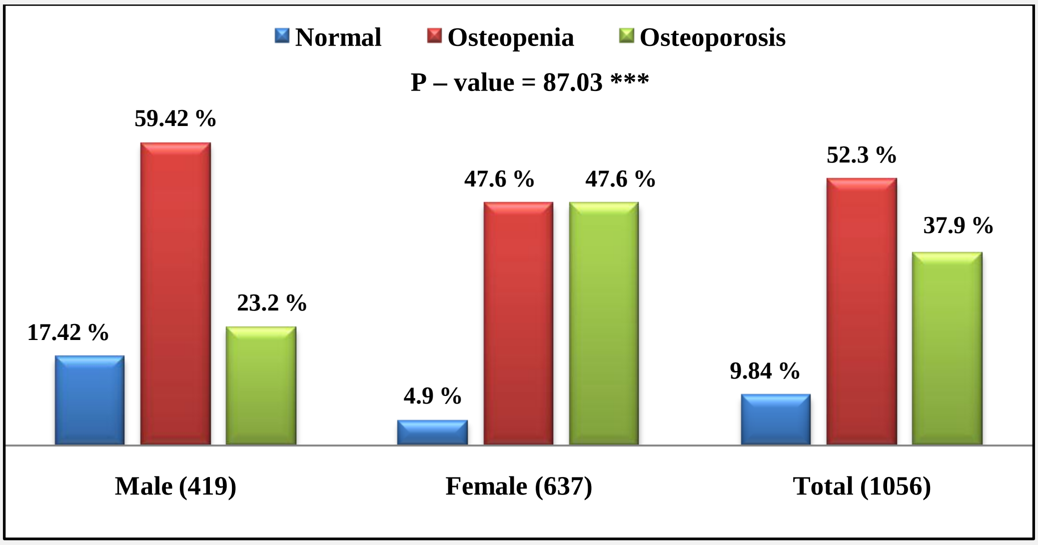
Table 4.1.3.2: Assessment of mean BMD corresponding to the age groups

Parameters	Age groups					
	60-69 years (809) [a]		70-79 years (206) [b]		≥80 years (41) [c]	
	Male (270)	Female (539)	Male (121)	Female (85)	Male (28)	Female (13)
Mean BMD	-1.8±0.85	-2.3±0.86	-1.8±0.96	-2.5±0.81	-2.0±0.77	-2.9±0.93
t – value [d]	a (M vs F) – 8.10 ***, b (M vs F) – 5.46 ***, c (M vs F) – 3.34 **					
P - value [e]	A+b+c (M vs M) – 0.63 [NS],[a+b (F vs F) – 0.04 *, a+c (F vs F) – 0.01 **, b+c (F vs F) – 0.15 [NS]] [f]					
Mean BMD	-2.15 ± 0.90		-2.11 ± 0.97		-2.26 ± 0.93	
P – value [e]	0.63					

d – student t test, e – analysis of variance, f – ANOVA LSD test, ** significant at <0.01, * significant at <0.001, NS = p – value > 0.01**

Data points in the column diagram - Figure 4.1.3.3 embodied 17.42% males and 4.9% females (total 9.84%) having normal BMD, 59.42% males and 47.6% females (total 52.3%) having osteopenia, 23.2% males and 47.6% females (total 37.9%) having osteoporosis. Prevalence of both osteopenia and osteoporosis was significantly higher among females compared to males (<0.001). Findings of the current study are an important addition to the existing data reported by Paul T *et. al.* (2012). This multi-centric study involved more than 3,500 subjects in South India reported a prevalence of osteoporosis at the spine and hip as 42.7% and 11.4%.

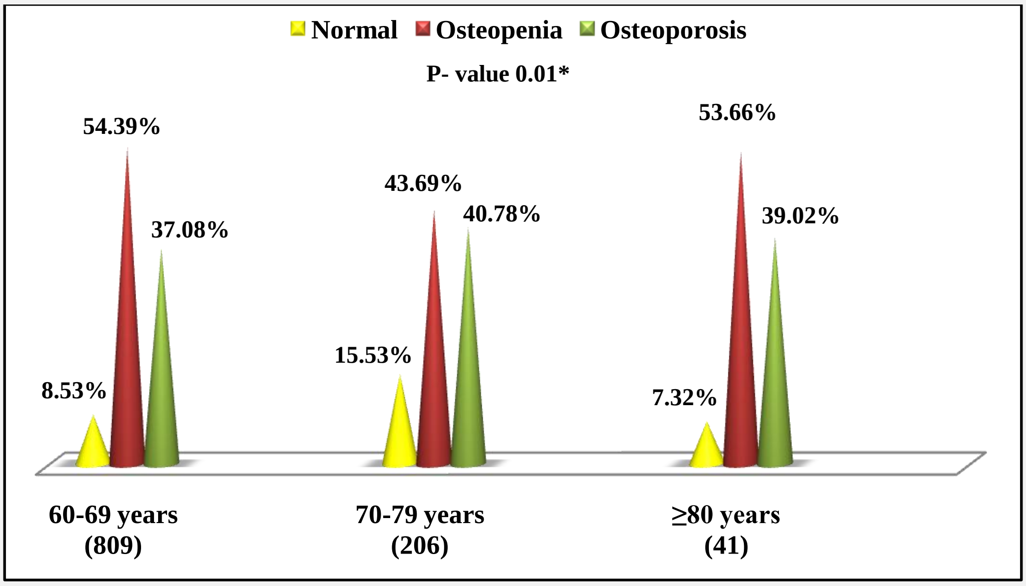
Figure 4.1.3.3: Magnitude of osteoporosis among the elderly subjects



Chi[2] test, * significant at <0.001**

Data plotted in the column diagram - Figure 4.1.3.4 depicted the association of poor bone health with age. In the young elderly age group 8.55%, in elderly age group 15.53% and in oldest elderly age group only 7.23% subjects possessed normal BMD. On the other hand, osteopenia was prevalent among 54.39% subjects in young elderly group, 43.69% in old elderly group and 53.66% in oldest elderly age group, respectively. Moreover, osteoporosis was prevalent among 37.08% subjects in young elderly age group, 40.78% in old elderly age group and 39.02% in oldest elderly age group, respectively. The mounted observation of this data was with advancement in age number of subjects with osteoporotic subjects was raised. Although the data also is showing a large number of osteopenic subjects in young elderly group, nevertheless, a large number of subjects included in this group is the reason behind it. Identical data was presented by Marwaha R. K. *et. al.* in 2011. In the study 792 males and 808 postmenopausal females (57.67±9.46 years) evidenced to have 35.1% (M-24.6%, F—42.5%) osteoporosis and 49.5% (M—54.3%, F—44.9%) osteopenia amongst them. It also evidenced that the prevalence of osteoporosis increased with age in females, but not in males.

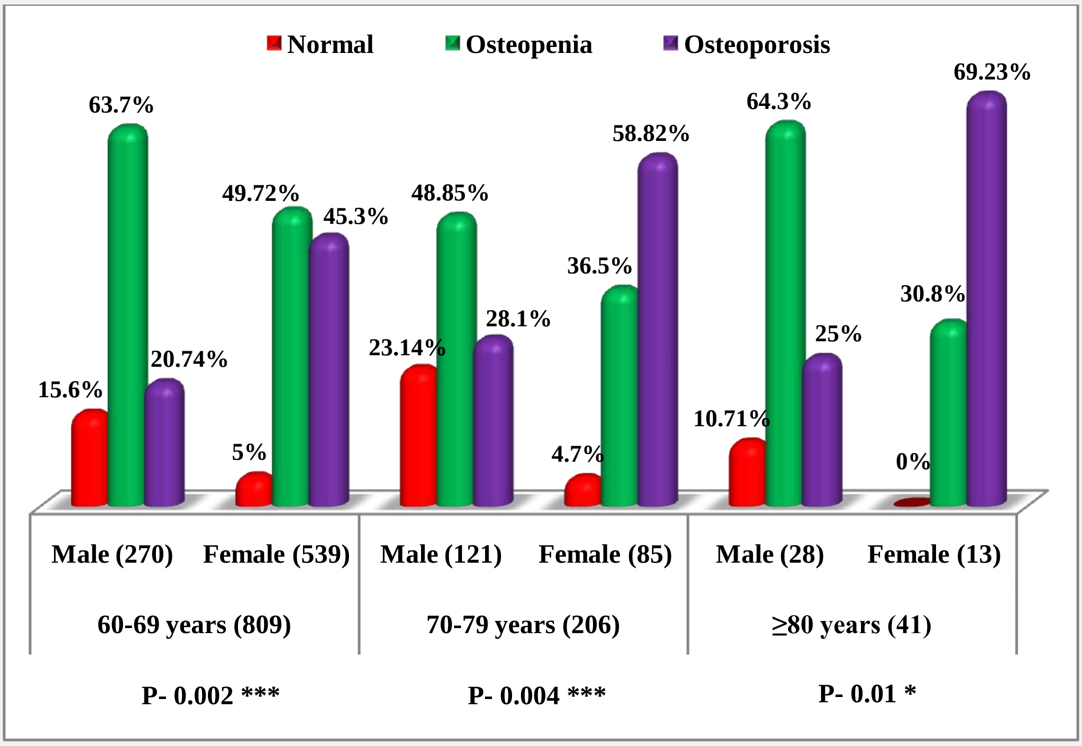
Figure 4.1.3.4: Age group-wise prevalence of osteoporosis



Chi^2 test, * significant at <0.05

With regard to screening the baseline subjects gender-wise and correlating the same with the magnitude of poor BMD lead to the observation that a very small number of subjects especially among females in young and old elderly age groups had normal BMD, i.e. 15.6% males and 5% females in young elderly group, 23.14% males and 4.7% females in old elderly group and 10.71% males in oldest elderly group. Likewise, a very high prevalence of osteopenia was detected among the subjects of all age category i.e. 63.7% males and 49.72% females in young elderly group, 48.8% males and 36.5% females in old elderly group, 64.3% males and 30.8% females in oldest elderly group. Osteoporosis too followed the same trend of having a high prevalence with two prominent influences. Influences here are age and gender. Magnitude of osteoporosis significantly increased with age and amongst females i.e. 20.74% males and 45.3% females in young elderly group, 28.1% males and 58.82% females in old elderly group, 7 (25%) males and 9 (69.23%) females in oldest elderly group were lying in the category of osteopenia (Figure 4.1.3.5). Marwaha RK *et. al.* (2011) documented a significant and consistent decreased in BMD at all sites in females with increasing age (<0.00001). In contrast, no such consistent pattern was observed in males.

Figure 4.1.3.5: Gender-wise prevalence of osteoporosis in each age group



Chi^2 test, * significant at <0.001, ** significant at <0.05**

4.1.4: Association of BMD with other parameters

Looking at the magnitude subjects in this section were segregated according to the BMD classification and analyzed to assess its association with other relevant parameters.

Table 4.1.4.1 is providing the data regarding the association of BMD if any with the baseline characteristics of the study population. Data showed an interesting thing i.e. osteopenia and osteoporosis was significantly less prevalent among the elderly engaged in jobs (p - <0.05). That gave a positive association between active life and bone health. Mean per capita income/ month (p - <0.01) and socioeconomic status (p - <0.01) were also found to be associated with bone health. Osteopenia and osteoporosis was prevalent significantly more among the subjects with low mean per capita income and among the subjects belonged to low income group compared to middle and high income group. Also, BMD showed a tendency of deterioration with increasing age, however, the association was not statistically significant (Figure 4.1.4.2). No other socio economic parameters showed significant association with BMD. Study by Shatrugna V *et. al.* (2005) substantiated that 29% of 289 women (30-60-year) belonged to low-income groups were osteoporosis at the femoral neck.

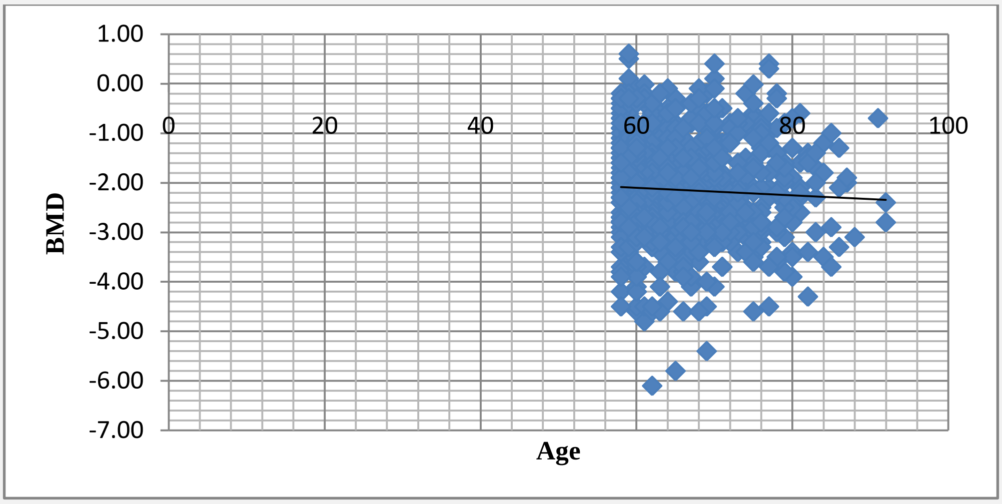
Table 4.1.4.1: Association of BMD with the baseline parameters

Parameters	Bone mass density			P – value ^{b}
	Normal (n=104)	Osteopenia (n=552)	Osteoporosis (n=400)	
Marital status				
Married	88 (84.62)	473 (85.69)	326 (81.50)	0.21 ^{NS}
Unmarried/ widow/Widower	16 (15.38)	79 (14.31)	74 (18.50)	
Type of family				
Nuclear	54 (51.92)	324 (58.70)	232 (58.00)	0.34 ^{NS}
Joint	44 (42.31)	215 (38.95)	156 (39.00)	
Extended	6 (5.77)	13 (2.36)	12 (3.00)	
Religion				
Hindu	103 (99.04)	546 (98.91)	393 (98.25)	0.63 ^{NS}
Muslin & others	1 (0.96)	6 (1.09)	7 (1.75)	
Employment				
Working	16 (15.38)	85 (15.60)	38 (9.50)	0.02 *
Non-working	88 (84.62)	467 (84.60)	362 (90.50)	
Education				
Illiterate/primary	19 (18.27)	103 (18.66)	73 (18.25)	0.53 ^{NS}
High school	31 (29.81)	205 (37.14)	154 (38.50)	

Graduation	54 (51.92)	244 (44.20)	173 (43.25)	
Per capita income	5822.8±4793.5 *a*	5566.6±50.24.8	4709.0±3694.3	0.005 ** *c*
Socio-economic status				
LIG	59 (56.73)	315 (57.07)	267 (66.75)	0.01**
MIG	30 (28.85)	181 (32.79)	101 (25.25)	
HIG	15 (14.42)	56 (10.14)	32 (8.00)	
Care giver				
Self	36 (34.62)	223 (40.40)	149 (37.25)	0.31 NS
Spouse/family	60 (57.69)	307 (55.62)	236 (59.00)	
Institution	8 (7.69)	22 (3.99)	15 (3.75)	
Knowledge of osteoporosis	36 (34.62)	233 (42.21)	182 (45.50)	0.12 NS
Knowledge of Ca	46 (44.23)	283 (51.27)	188 (47.00)	0.25 NS

Figures in the parenthesis denote percentage of subjects, a - mean ± SD, b - Chi^{2} test, c – Analysis of variance, *significant at <0.05, **significant at <0.01, NS = p – value > 0.01

Figure 4.1.4.2 Association of BMD and age



Data regarding the physical activity showed that the mean time spent after exercise (p - <0.05) and yoga (p - <0.01) was significantly less among the subjects with osteopenia and osteoporosis; it was relatively decreasing among the osteopenic subjects followed by osteoporotic subjects (Table 4.1.4.3). No other activities and addiction or habits such as smoking, alcohol consumption etc. evidenced any association with BMD. Thus, the inference that can be derived here is physical activity and osteoporosis walks in a "vice-versa" way; less activity promotes bone health deterioration and osteoporosis restricts activities. Also, routine physical activity is an important and unavoidable part of bone health care. Impact of leading a sedentary lifestyle on bone health has been well evidenced in different part of the world. One such study was conducted by Fatima M *et. al.*, in 2009, and documented that 72% Pakistani women lead a sedentary lifestyle and high prevalence of osteopenia and osteoporosis was observed amongst them. Jha R *et. al.* (2010) had explained tea as a popular beverage consumed by the Indian population. However, he also pointed that due to the high caffeine content, evidences suggested an association with a greater risk of hip fracture.

Table 4.1.4.3: Association of BMD with daily activities and habits

Parameters	**Bone mass density**			**P – value** [c]
	Normal (n=104)	**Osteopenia (n=552)**	**Osteoporosis (n=400)**	
Leisure activities	5.27 ± 1.80 [a]	5.31 ± 1.60	5.34 ± 1.76	0.65 [NS]
Exercise [d]	0.49 ± 0.465	0.44 ± 0.443	0.39 ± 0.414	0.06*
Yoga [d]	0.10 ± 0.25	0.09 ± 0.23	0.05 ± 0.16	0.01**
Social recreation	3.23 ± 1.97	3.01 ± 1.75	3.10 ± 1.70	0.14 [NS]
Sleep/rest	9.20 ± 1.88	9.40 ± 1.81	9.48 ± 1.93	0.37 [NS]
Idle time	5.19 ± 2.01	5.01 ± 2.10	5.15 ± 2.54	0.57 [NS]
Total active time	4.00 ± 2.47	4.19 ± 2.29	3.86 ± 2.15	0.09 [NS]
Total inactive time	22.89 ± 2.56	22.73 ± 2.36	20.08 ± 2.12	0.07 [NS]
Habits				**P – value** [e]
Smoking	0 (0.0) [b]	7 (1.27)	0 (0.0)	0.11 [NS]
Alcohol	103 (99.04)	543 (98.37)	398 (99.5)	0.45 [NS]
Tobacco	6 (5.77)	29 (5.25)	19 (4.75)	0.98 [NS]
Snuff	4 (3.85)	23 (4.17)	21 (5.25)	0.88 [NS]
Tea/coffee	89 (94.23)	524 (94.93)	377 (94.25)	0.21 [NS]

Figures in the parenthesis denote percentage of subjects, *a* = mean ± SD, *b* = number/ %
c – Analysis of variance, d – Kruskal Wallis test, e – Chi^2 test, * significant at <0.05, ** significant at <0.05, NS = p – value > 0.01

Anthropometric data (Table 4.1.4.4) of the elderly subjects showed an attention-grabbing association with BMD. Mean height of the subjects with normal BMD was significantly high and steadily reduced with deterioration in BMD (p - <0.001). Thus, indicated a positive association between short stature and poor BMD. Besides, hip circumference (p - <0.05) and waist hip ratio (p - <0.001) were also found to be significantly associated with BMD. Hip circumference was found to be increasing with the decreasing bone health. It was also observed that the 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. There is an excellent study which found facts similar to our findings.

Height was predicted as important determinant of bone mineral content among 289 Indian women in the 30-60-year age group (Shatrugna V *et. al.* 2005).

Table 4.1.4.4: Association of BMD with anthropometric parameters

Parameters	Bone mass density			P – value [c]
	Normal (n=104)	**Osteopenia (n=552)**	**Osteoporosis (n=400)**	
Weight	65.80 ± 11.09 [a]	65.20 ± 12.92	64.26 ± 13.70	0.27 NS
Height	158.82 ± 9.1	155.87 ± 9.3	152.50 ± 11.1	ab-0.005** ac-0.001*** bc-0.001***
BMI	26.19 ± 4.62	26.92 ± 5.14	27.64 ± 6.32	ac-0.01**
BMI category [d]				
Underweight	4 (3.85) [b]	10 (1.81)	9 (2.25)	0.52 NS
Normal	16 (15.38)	108 (19.57)	66 (16.50)	
Over weight	22 (21.15)	105 (19.02)	68 (17.00)	
Obese	62 (59.62)	329 (59.60)	257 (64.25)	
Waist	78.83 ± 25.49	79.01 ± 25.36	81.21 ± 26.23	0.39 NS
Hip	84.94 ± 28.50	86.87 ± 27.15	91.32 ± 28.70	0.024*
WHR	0.99 ±0.66	0.91 ± 0.10	0.90 ± 0.14	0.001***
WHR class				
Normal	27 (25.96)	180 (32.61)	164 (41.00)	0.003***
At risk	77 (74.04)	372 (67.39)	236 (59.00)	

Figures in the parenthesis denote percentage of subjects, a - mean ± SD, b - number/ %, c – Analysis of variance, d – Chi^2 test, * significant at <0.05, ** significant at <0.01, * significant at <0.001, NS = p – value > 0.01**

Table 4.1.4.5 depicted the data regarding the chronic health issues of the study population. Data could not produce any significant association of chronic health problems with BMD. However, problems with central nervous system were found to be more prevalent (significant) among 11.96% osteopenic subjects and 18.75% osteoporotic subjects. It was also observed that the locomotor problems such as pain in knees and other joints, difficulties in mobility and performing physical activity tasks etc. were prevalent significantly more among the 47.28% osteopenic subjects and 48.50% osteoporotic subjects. In this context a recent study from Rohtak district (North India) can be quoted here. The study evidenced an annual fracture incidence rate of 163 and 121 per 100,000 per year in women and men (≥50 years), respectively (Dhanwal DK et. al., 2013).

Table 4.1.4.5: Association of BMD with the chronic health problems

Parameters	Bone mass density			P – value [d]
	Normal (n=104)	Osteopenia (n=552)	Osteoporosis (n=400)	
Oral	18 (17.31)	99 (17.93)	78 (19.50)	0.78 NS
Respiratory	6 (5.77)	42 (7.61)	28 (7.00)	0.78 NS
GI	15 (14.42)	92 (16.67)	70 (17.50)	0.75 NS
Hepato biliary	3 (2.88)	6 (1.09)	6 (1.50)	0.35 NS
Pancreas	3 (2.88)	9 (1.63)	6 (1.50)	0.61 NS
Endocrine	4 (3.85)	37 (6.70)	36 (9.00)	0.14 NS
CVD	22 (21.15)	97 (17.57)	88 (22.00)	0.21 NS
Genito-urinal	1 (0.96)	18 (3.26)	10 (2.50)	0.39 NS
Locomotor	37 (35.58)	261 (47.28)	194 (48.50)	0.05 NS
CNS	11 (10.58)	66 (11.96)	75 (18.75)	0.006 **
Diabetes	26 (25.00)	117 (21.20)	94 (23.50)	0.56 NS
Fractures				
1 time	24 (23.08)	122 (22.10)	99 (24.75)	0.91 NS
2-3 times	4 (3.85)	22 (3.99)	14 (3.50)	
Site of fracture				
Hip	3 (2.88)	31 (5.62)	20 (5.00)	0.89 NS
Wrist	13 (12.50)	56 (10.14)	52 (13.00)	
Vertebra	3 (2.88)	18 (3.26)	17 (4.25)	
Ankle	4 (3.85)	17 (3.08)	9 (2.25)	
Knee	4 (3.85)	22 (3.99)	15 (3.75)	
Systolic BP				
Pre hypertension I [a]	54 (51.92)	327 (59.24)	238 (59.50)	0.84 NS e
Hypertension I [b]	26 (25.00)	118 (21.38)	87 (21.75)	
Hypertension II [c]	5 (4.81)	29 (5.25)	20 (5.00)	
Mean BMD	a= -2.16±0.86, b= -2.11±1.0, c= -2.22±0.94, non-hypertensive= -2.05±0.94			0.47 NS
Diastolic BP				
Pre hypertension I [a]	39 (37.50)	190 (34.42)	141 (35.25)	0.73 NS
Hypertension I [b]	34 (32.69)	189 (34.24)	124 (31.00)	
Hypertension II [c]	11 (10.58)	56 (10.14)	54 (13.50)	
Mean BMD	a= -2.13±0.93, b= -2.11±0.93, c= -2.21±0.84, non-hypertensive= -2.14±0.87			0.82 NS e

Figures in the parenthesis denote percentage of subjects, d - Chi2 test, e – Analysis of variance, ** significant at <0.01, NS = p – value > 0.01

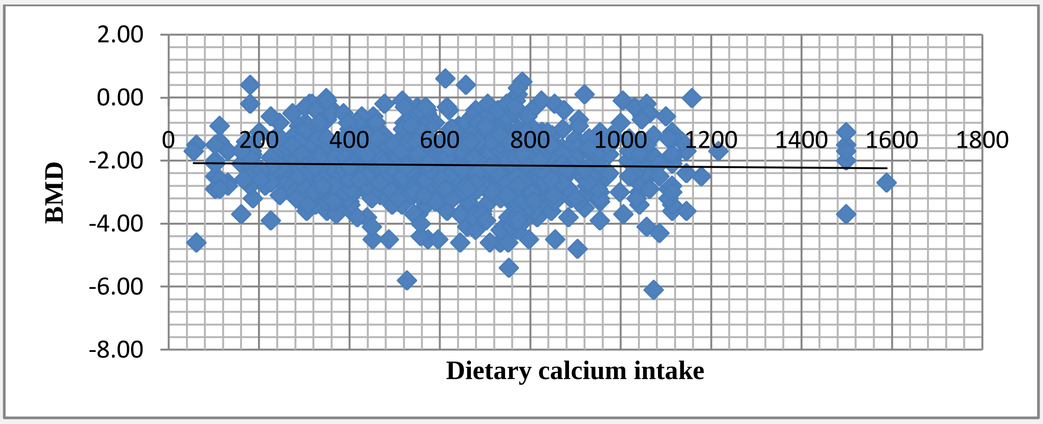
Data on food habits and nutrient intake has been presented in table 4.1.4.6. Observations drawn from the data were an insignificant association between nutrient intake and poor BMD, yet β carotene showed a significantly less intake among the osteopenic and osteoporotic subjects. Ca intake was found to be extremely low and it may serve the possible reason of high prevalence of osteoporosis; however, the correlation was not significant (Figure 4.1.4.7). In a study Coin A *et. al.* (2008) tried to assess the correlation among dietary intake, nutritional indices and hip bone mineral density (BMD) among 352 outpatient elderly aged 73.5±75.3 years. By applying multiple regression analysis, they found the variables that retained their independent explanatory role on total hip BMD, were BMI and protein intake in men, and BMI and albumin in women. By logistic regression analysis, men risked having a low BMD with a BMI o22 (OR ¼ 12) and a protein intake o65.7 g/day (OR ¼ 3.7).

Table 4.1.4.6: Association of BMD with dietary habit and nutrient intake

Parameters	Bone mass density			P – value [f]
	Normal [a] (n=104)	Osteopenia [b] (n=552)	Osteoporosis (n=400) [c]	
Vegetarian	102 (98.08) [d]	540 (97.83)	391 (97.75)	0.97 NS
Consumption of meal				
Less	3 (2.88)	14 (2.54)	21 (5.25)	0.15 NS
Adequate	99 (95.19)	535 (96.38)	371 (92.75)	
Nutrient intake [g]				
Energy (Kcal)	1259±294[e]	1228±275	1214±234	0.55 NS
Protein (gm)	35.22 ± 10.54	35.86 ± 11.21	34.87 ± 9.27	0.64 NS
Fat (gm)	43.60 ± 9.70	41.48 ± 10.12	41.36 ± 9.98	0.11 NS
Iron (mg)	10.97 ± 4.31	10.65 ± 4.02	10.32 ± 4.14	0.26 NS
Calcium (mg)	617±219	634.±241	625±234	0.91 NS
Vitamin C (mg)	78.81 ± 56.90	64.68±45.72	67.58±47.06	0.10 NS
β carotene [h]	1200±252	1122±291	1099± 305	ab-0.005 ** ac-0.003 **

Figures in the parenthesis denote percentage of subjects, *d* - number/ %, e - mean ± SD, f – Chi^2 test, g – Analysis of variance, h – ANOVA LSD test, ** significant at <0.05, NS = p – value > 0.01

Figure 4.1.4.7 Association of BMD and dietary Ca intake



4.1.5: Activity pattern of the elderly subjects

24 hours activity recall was noted, that included Daily activity leisure time, exercise, yoga, social recreation, sleep/rest, idle time, total active time and total inactive time.

When subjects were segregated according to gender, data gave a scope to visualize the daily activities of the study population (4.1.5.1). Female spent significantly (<0.001) more time (male: 2.9±2.10 and female: 4.0±2.4) in daily activities. Exercise and Yoga were the two activities given the smallest length of time by both males and females, especially by the females (yoga: 0.06±0.20, exercise: 0.40±0.44) compared to males (yoga: 0.10±0.23, exercise: 0.48±0.43) (p- 0.004). Moreover, the mean active time and inactive time spent by the subjects were far different from each other i.e. 4.04±2.3 hours and 19.9±2.3 hours and males spent significantly more time inactively (p - <0.001). Subjects in young elderly group spent their maximum time inactively (19.67 ± 3.35). Apart from that they spent 3.75 ± 2.29 hours in daily activities, 0.44 ± 0.443 hours for exercises and 0.07 ± 0.21 hours for yoga. Subjects in older elderly group also spent their maximum time inactively (20.44 ± 2.13) and by sleeping (8.47 ± 1.85). Besides, they spent 3. 3.03 ± 2.03 hours in daily activities, 4.44 ± 1.79 and 5.15 ± 2.23 hours in leisure activities and idly and a very less time i.e. 3.50 ± 2.11 hours for active physical activities, including 0.40 ± 0.417 hours for exercises and 0.08 ± 0.21 hours for yoga. Subjects in oldest elderly group spent their maximum time inactively (21.46 ± 1.71) and a very less time i.e. 2.53 ± 1.63 hours actively. It was also observed that with increase in age daily activities, exercise and active time were significantly decreased. On the contrary, with increase in age mean time for social recreation, sleep and inactivity also increased significantly. However, there was no significant difference among the three age groups in spending time after leisure activities, yoga and idle activities. In this context, WHO's (2011) given elaborated guidelines of physical activities for older adults which should be brought to the knowledge of elderly population. According to the guidelines at least 150 minutes of moderate-intensity aerobics should be done by older adults throughout the week or they should do vigorous intensity aerobics at least for 75 minutes throughout the week or a corresponding combination of both. Aerobic activity should be performed short breaks of 10 minutes duration.

Table 4.1.5.1 Mean time in hours spent after different activities by the elderly subjects

Parameters	Gender		P – value [a]	Age groups			P – value [b]
	Male (419)	Female (637)		60-69 years (809) [a]	70-79 years (206) [b]	≥80 years (41) [c]	
Daily activity	2.9±2.1	4.0±2.4	8.54 ***	3.75 ± 2.29	3.03 ± 2.03	2.21 ± 1.60	ab - 0.001 ac - 0.001 bc - 0.030
Leisure time	4.4±1.68	4.2±1.71	2.40 *	4.30 ± 1.67	4.44 ± 1.79	4.16 ± 1.96	0.45 [NS]
Exercise	0.48±0.43	0.40±0.44	2.87 **	0.44 ± 0.44	0.40 ± 0.41	0.24 ± 0.318	ac= 0.004 bc= 0.035
Yoga	0.10±0.23	0.06±0.20	2.97 **	0.07 ± 0.21	0.08 ± 0.21	0.08 ± 0.24	0.97 [NS]
Social recreation	2.5±2.0	1.8±1.5	2.92 ***	1.98 ± 1.73	2.39 ± 1.75	2.46 ± 2.05	ab= 0.002
Sleep/rest	8.38±2	8.44±1.8	0.88 [NS]	8.33 ± 1.78	8.47 ± 1.85	9.80 ± 2.76	ac= <0.001 bc= <0.001
Idle time	5.2±2.02	5±2.4	2.65 **	5.07 ± 2.29	5.15 ± 2.23	5.03 ± 1.97	0.32 [NS]
Active time	3.5±2.17	4.4±2.24	7.50 ***	4.27 ± 2.28	3.50 ± 2.11	2.53 ± 1.63	ab= <0.001 ac= <0.001 bc= 0.010
Inactive time	20.5±2.2	19.5±2.3	7.06 ***	19.67 ± 3.35	20.44 ± 2.13	21.46 ± 1.71	ab= <0.001 ac= <0.001 bc= 0.009

a – student t test, b – ANOVA LSD test, *significant at <0.05, **significant at <0.01, * significant at <0.001, NS = p – value > 0.01**

4.1.6: Anthropometric measurements of the subjects

Anthropometric measurements included height, weight, BMI, waist circumference, hip circumference and WHR. Association of anthropometric parameters with age and gender was assessed in this section.

Anthropometric measurements of the subjects are presented in Table 4.1.6.1. The table depicted that males possessed all the baseline anthropometric measurements such as weight, height, waist, hip and waist-hip ratio significantly higher than females, as expected. Besides, mean BMI of male subjects was also found to be high (male: 25.31±4.26, female: 28.85±14.95) and waist- hip ratio too (male: 0.94±0.10, female: 0.89±0.29). This indicated a further tendency of having central obesity among the males included in the study. Age wise classification illustrated that the weight and BMI showed a significant reducing trend with advancement in age. Contrasting weight and BMI, waist circumference, hip circumference and WHR increased showed a tendency of increasing with advancement of age, however, they were not statistically significant. A study by Coin A *et. al.* (2008) explained the relation of BMI and BMD adequately. Author mentioned that BMI of 352 elderly outpatients (216 women aged 73.5±75.3 years and 136 men aged 73.9±75.6 years) <22 were normal for younger adults but carry a higher risk of osteoporosis in the elderly, particularly in women.

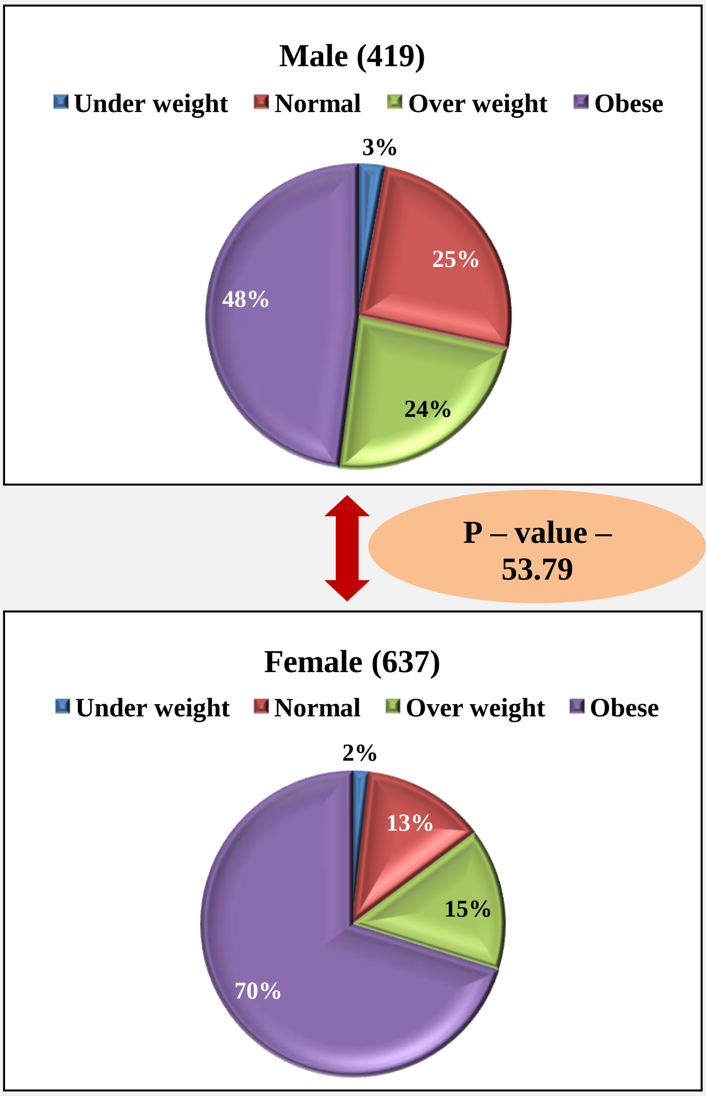
Table 4.1.6.1: Mean anthropometric measurements of the subjects

Parameters	Male (419)	Female (637)	t – value [d]	60-69 years (809) [a]	70-79 years (206) [b]	≥80 years (41) [c]	P– value [e]
Weight (kg)	66.30±12.47	63.98±13.36	3.06 **	65.57 ± 12.64	63.81 ± 14.05	57.20 ± 13.41	ab-0.028* ac-0.001*** bc-0.002**
Height (cms)	161.8±7.82	150.34±8.93	22.30 ***	154.5 ± 9.61	156.30 ± 12.03	154.87 ± 10.8	ab-0.025**
BMI (kg/m^2)	25.31±4.26	28.85±14.95	8.77 ***	27.60 ± 5.75	27.57 ± 24.69	23.70 ± 4.22	ac-0.042*
Waist (cms)	85.70±23.5	75.97±26.34	6.12 ***	78.89 ± 26.5	82.56 ± 23.17	84.57 ± 19.5	0.09 [NS]
Hip (cms)	90.86±23.7	86.66±30.32	2.39 *	87.65 ± 29.1	90.39 ± 24.57	91.35 ± 18.6	0.35 [NS]
WHR (WC/HC)	0.94 ± 0.10	0.89 ± 0.29	3.45 **	0.91 ± 0.26	0.92 ± 0.10	0.92 ± 0.08	0.93 [NS]

d – Student t test, e – ANOVA LSD test, f – Analysis of variance, *significant at <0.05, **significant at <0.01, ***significant at <0.001, NS = p – value > 0.01

Figure 4.1.6.2 depicted that the prevalence of obesity was considerably high among the study population i.e. 61.36%, moreover it was significantly higher among the elderly females (70.17%) compared to males (47.97%). Besides, over weight was found to be prevalent among 18.46% subjects with an angle towards male. With the similar background a study was conducted by Salamat MR *et. al* (2013) and a inconsistent association between body mass index (BMI) and bone mineral density (BMD) was evidenced. In the study 230 Iranian men of 50-79 years were divided into two groups i.e. normal weight: <25.0 kg/m^2 and overweight and obese: ≥25 kg/m^2. They found that among 95 men with BMI < 25 kg/m2, 58.9% (95% CI: 48.4, 68.9) had osteopenia and 34.7% (95% CI: 25.3, 45.2) had osteoporosis, respectively.

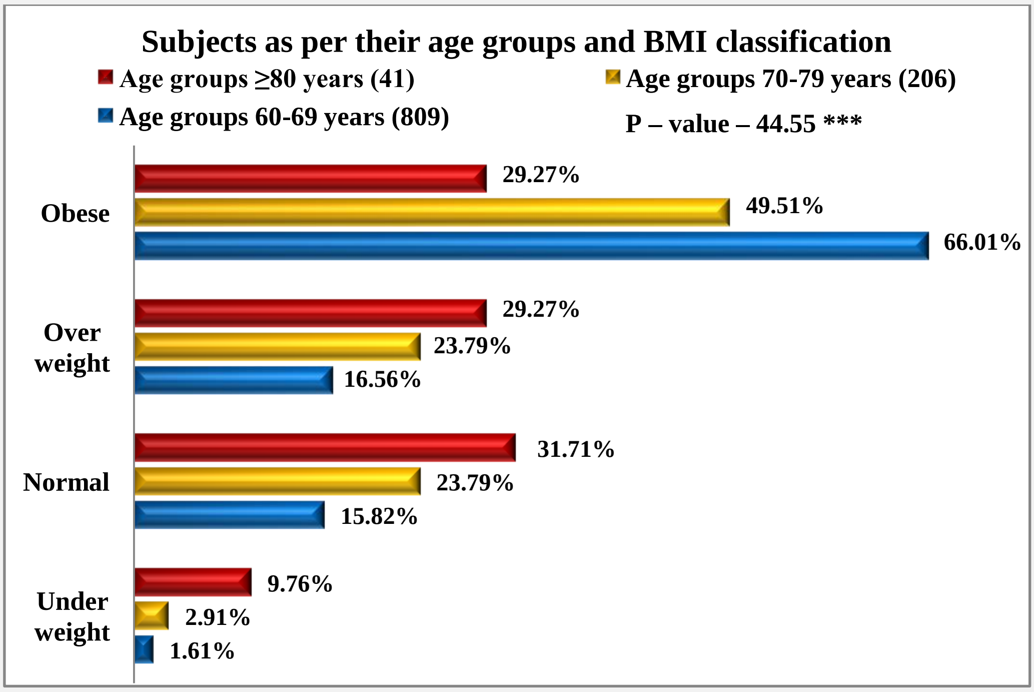
Figure 4.1.6.2: BMI and gender-wise distribution of subjects



Chi^2 test, * significant at <0.001**

When the subjects were classified according to their age and correlated with BMI, it was observed that obesity and overweight were predominantly prevalent among 66.01% and 16.56% young elderly; however, the number of oldest elderly subjects was less though (Table 4.1.6.3). Relation of BMI and BMD with age as a risk factor has been explained well in a study conducted by Fawzy T. *et. al*. (2011). In the study among 101 subjects in Ajman, UAE, BMD was found low in 82.4% people with normal BMI, in 78.1% with overweight, and in 44.2% with obesity (P < .001). They also observed an association between advancing age and lower BMI as an important risk factor in the occurrence of low BMD.

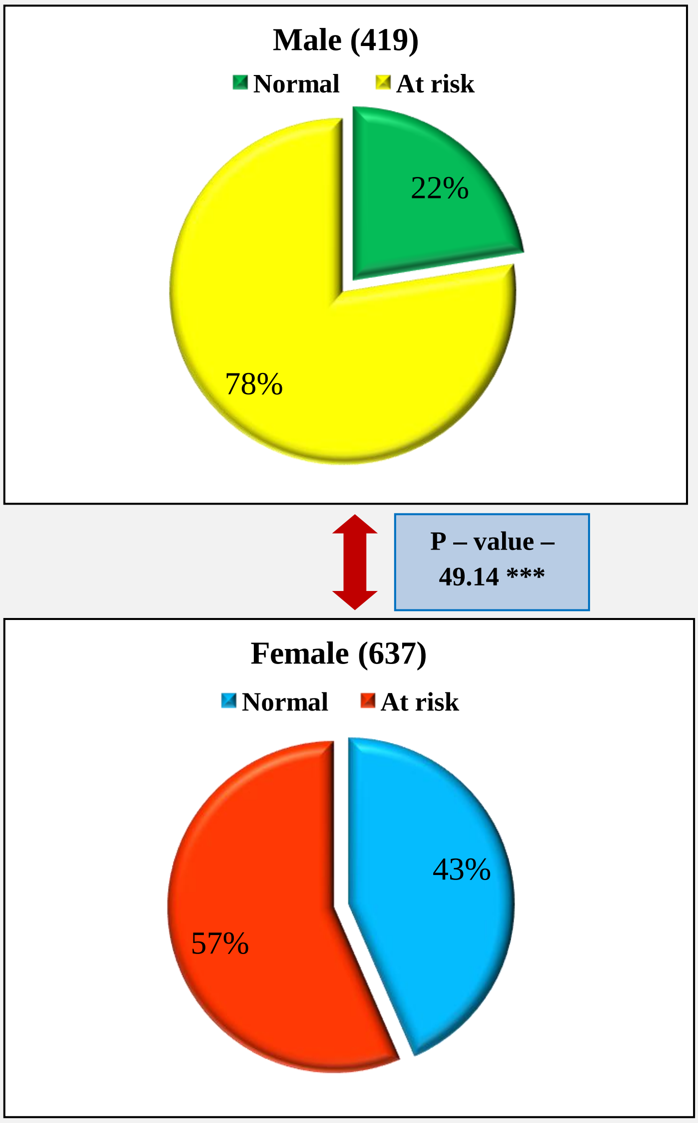
Figure 4.1.6.3: BMI and age group-wise distribution of subjects



Chi^2 test, * significant at <0.001**

Data presented in the pie chart 4.1.6.4 is showing the waist – hip of the study population. The diagram demonstrated that 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). In a study BMD was documented to be significantly correlated to weight, height, body mass index and waist-to-hip ratio (P< 0.001) among 4445 Iranian males and females with an age ranging from 20 to 70 years. The study also documented that the existing association between anthropometric parameters and BMD was regardless of the location of BMD measurement and it was stronger for WHR and weight (correlation coefficient was equal to 0.315 for WHR, 0.337 for weight and 0.191 for BMI) (Meybodi HRA, 2011).

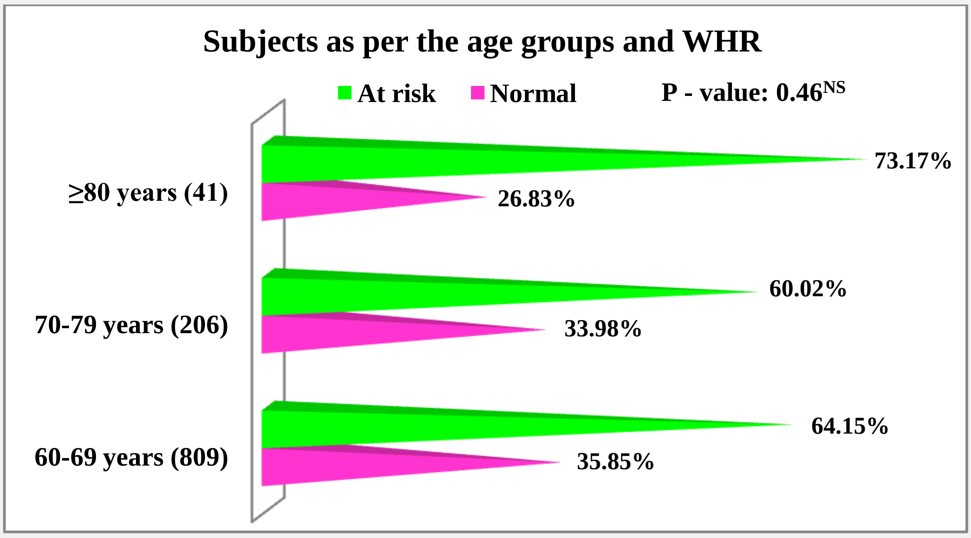
Figure 4.1.6.4: WHR and gender-wise distribution of subjects



Chi^2 test, * Significant at <0.001**

After classifying the subjects according to their age and associated with WHR, it was observed that 73.17% subjects in oldest elderly group were at risk category of WHR. However, the percentage prevalence of central obesity in oldest elderly group was not significantly different than other two age groups and also the number of subjects in oldest elderly age group was less than the other two groups (Figure 4.1.6.5). In favour of the current findings a study concluded by Kerrie L. *et. al.* (2012) is just ideal to talk about. In this study 132 healthy women residing in New York City were classified in premenopausal (n=33, 22–43 yr), perimenopausal (n=42, 43–56 yr) and postmenopausal (n=57, 49–70 yr); and observed that WHR increased with advancing age i.e. premenopausal (0.79 ± 0.06), perimenopausal (0.80 ± 0.06), and postmenopausal (0.82 ± 0.08), respectively.

Figure 4.1.6.5: WHR and age group-wise distribution of subjects



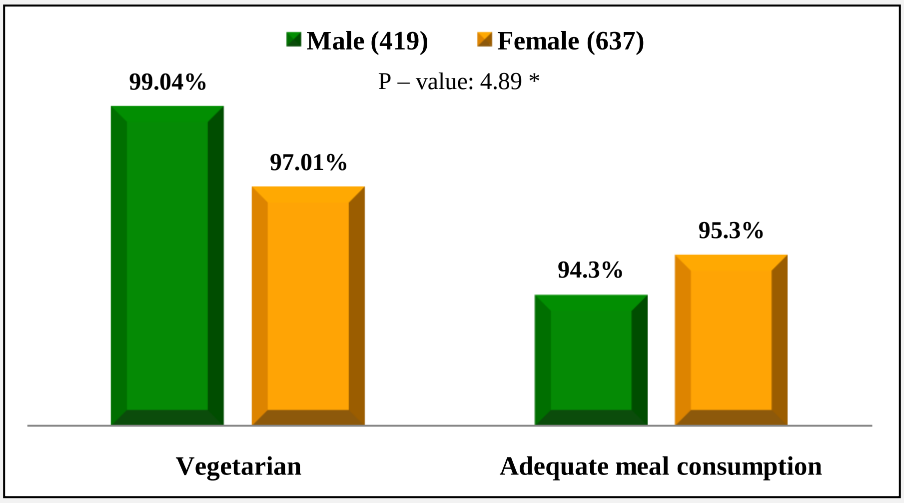
NS = p – value > 0.01

4.1.7: Dietary pattern of the subjects

Dietary pattern, nutrient intake and their association with age and gender were assessed in this section. An average of three days dietary recall (24 hour dietary recall) and food frequency were taken for the analysis.

The bar diagram 4.1.7.1 depicts that 99.04% males and 97.82% females were lacto-vegetarian and 94.3% males among 94.9% females adequate meals. With the aim to assess the possible impact of a vegetarian diet on bone mineral density, two groups of Slovak vegetarian and non-vegetarian women were assessed. The results showed vegetarian subjects had a significantly lower TrFBMD ($p < 0.05$) compared to the non-vegetarians (Krivošíková Z. *et. al*., 2010).

Figure 4.1.7.1: Meal consumption of the baseline subjects



Chi^2 test, * significant at <0.05

Table 4.1.7.2 is representative of micro and macro nutrient intake. It was noted from the table that mean calorie and β carotene intake was not found to be significantly different among males and females. However, protein (p - <0.001), fat (p - <0.01), calcium (p - <0.001) and vitamin C (p - <0.05) intake appeared to be significantly high amongst females and yet iron intake was significantly high (p - <0.001) among males. Based on the age group-wise classification and nutrient intake observation was made that fat, calcium, vitamin C and β carotene intake wasn't significantly different amongst males than females. However, calorie intake showed an increasing fashion with advancing age (p- <0.05). Unlike calorie, protein (p- <0.01) and iron (p- <0.05) intake showed a declining fashion with advancing age. Thus, a noticeable point arising here is that mean calorie intake got reduced with advancing age significantly which may have played a role for the intake of other important nutrient to be less among the older elderly and oldest elderly; hence together contributed to the increased BMD with advancing age. Similar inference was made by Mehta P. and Shrinagarpure B (2000) in a study with 320 elderly men and women belonged to LIG, MIG and HIG group, residing in Urban Baroda. Nutrient intake of elderly men of all the income groups revealed lower consumption of energy, protein, iron and beta-carotene compared to the RDA; in contrast fats and vitamin C intakes were higher as compared to the RDA (p < 0.05).

Table 4.1.7.2: Mean nutrient intake of the baseline subjects

Indices	Male (419)	Female (637)	P- value [a]	60-69 years (809)	70-79 years (206)	≥80 years (41)	P- value [b]
Energy (Kcal)	1215 ± 305	1233 ± 230	1.80 NS	1232 ± 262	1218 ± 250	1139 ± 315	0.01 *
Protein (gm)	33.84 ± 12.85	36.45 ± 8.45	5.69 ***	35.92 ±10.40	34.16 ± 10.19	31.88 ± 11.72	0.002 **
Fat (gm)	40.42 ± 10.13	42.44 ± 9.13	3.04 **	41.87 ± 9.87	40.85 ± 10.39	41.11 ± 12.2	0.31 NS
Iron (mg)	11.42 ± 5.07	9.98 ± 3.18	4.56 ***	10.49 ± 3.74	11.07 ± 5.25	9.40 ± 4.15	0.02 *
Calcium (mg)	589 ± 246	655 ± 226	4.96 ***	639 ± 237	601± 233	576 ± 225	0.08 NS
Vitamin C (mg)	63.90 ± 48.91	69.31± 46.58	2.55 *	68.44 ± 48.06	60.71 ± 42.96	74.75 ± 57.2	0.11 NS
β- carotene	1128 ± 236	1116 ± 327	1.83 NS	1121 ± 301	1118 ± 275	1124 ± 235	0.93 NS

a- Student t test, b – Analysis of variance test, *significant at <0.05, **significant at <0.01, * significant at <0.001, NS = p – value > 0.01**

Table 4.1.7.3 represents the number of subjects consumed some particular percentage of RDA. In gender-wise classification 53.7% males and 51.5% females could meet 50-75% RDA of calorie; 30.31% males and 37.51 females could meet 76-100% RDA of calorie. Likewise, 39.14% males and 58.6% females could meet 50-75% RDA of protein and only 12.64% males and 16.64% females could meet 50-75%. Fat intake was observed very high among the study population i.e. 79.71% males 86.02% females met >100% RDA of fat. On the other hand iron showed comparatively less intake i.e. only 10.3% males 3.92% females could meet 51-75% RDA. 51-75% RDA of calcium was met by 33.7% males and 49.3% females. RDA of vitamin C and β carotene was met by more than 50%and around 60% subjects in both the genders. Age-wise classification of the subjects grippingly showed a dropping trend in percentage of subjects meeting 51-75% or 76-100% RDA of almost all the nutrients included in the analysis (statistically significant). Thus, the data indicated age is affecting the nutrient intake significantly and the combined effect of age and inadequate nutrient intake may act as a risk factor for osteoporosis.

Table 4.1.7.3: Percent RDA consumption of various nutrients among the baseline subjects

% RDA	Male (419)	Female (637)	P – value [a]	60-69 years (809)	70-79 years (206)	≥80 years (41)	P – value [a]
Energy intake							
<25	4 (1)	4 (0.62)	0.01 *	5 (0.62)	0 (0)	1 (2.44)	0.06 NS
25 to 50	52 (12.41)	46 (7.22)		96 (11.87)	28 (13.59)	9 (21.95)	
51 to 75	225 (53.7)	328 (51.5)		396 (48.95)	105 (50.97)	19 (46.34)	
76 to 100	127 (30.31)	239 (37.51)		294 (36.34)	63 (30.58)	12 (29.27)	
>100	10 (2.4)	20 (3.13)		18 (2.22)	10 (4.85)	0 (0)	
Protein							
<25	23 (5.5)	36 (5.7)	0.0001 ***	20 (2.47)	8 (3.88)	3 (7.32)	0.01 *
25 to 50	173 (41.3)	122 (19.2)		174 (21.51)	60 (29.13)	16 (39.02)	
51 to 75	164 (39.14)	373 (58.6)		479 (59.21)	112 (54.37)	18 (43.90)	
76 to 100	53 (12.64)	106 (16.64)		128 (15.82)	26 (12.62)	4 (9.76)	
>100	6 (1.43)	00 (00)		8 (0.99)	0 (0)	0 (0)	
Fat							
<25	00 (00)	00 (00)	0.01 **	0 (0)	0 (0)	0 (0)	0.30 NS
25 to 50	5 (1.2)	9 (1.41)		8 (1.01)	2 (0.98)	2 (4.88)	
51 to 75	11 (2.62)	27 (4.23)		15 (1.89)	5 (2.44)	2 (4.88)	
76 to 100	69 (16.5)	53 (8.32)		79 (9.95)	22 (10.73)	4 (9.76)	
>100	334 (79.71)	548 (86.02)		692 (87.15)	176 (85.85)	33 (80.49)	
Iron							
<25	68 (16.22)	132 (20.72)	0.0001	126 (15.77)	38 (19)	18 (43.90)	0.001

25 to 50	292 (69.7)	478 (75.03)	***	619 (77.47)	139 (69.5)	19 (46.34)	***
51 to 75	43 (10.3)	25 (3.92)		45 (5.63)	18 (9)	4 (9.76)	
76 to 100	10 (2.4)	1 (0.2)		7 (0.88)	5 (2.5)	0 (0)	
>100	6 (1.43)	1 (0.2)		2 (0.25)	0 (0)	0 (0)	
Calcium							
<25	54 (12.9)	46 (7.22)	0.0001 ***	65 (8.33)	15 (7.46)	5 (12.50)	0.02 *
25 to 50	177 (42.24)	208 (32.7)		270 (34.62)	98 (48.76)	17 (42.50)	
51 to 75	141 (33.7)	314 (49.3)		361 (46.28)	65 (32.34)	15 (37.50)	
76 to 100	44 (10.5)	65 (10.2)		83 (10.64)	23 (11.44)	3 (7.50)	
>100	3 (0.71)	4 (0.62)		1 (0.13)	0 (0)	0 (0)	
Vitamin C							
<25	27 (6.44)	60 (9.41)	0.04 *	43 (5.40)	0 (0)		0.34 NS
25 to 50	45 (10.73)	71 (11.1)		52 (6.52)	3 (7.50)		
51 to 75	47 (11.21)	22 (3.5)		94 (11.79)	4 (10)		
76 to 100	54(12.9)	21 (3.3)		93 (11.67)	7 (17.50)		
>100	246 (58.71)	343 (53.84)		515 (64.62)	26 (65)		
B Carotene							
<25	4 (1)	3 (0.5)	0.49 NS	3 (0.37)	0 (0)	0 (0)	0.91 NS
25 to 50	265 (63.24)	373 (58.6)		493 (61.17)	123 (59.71)	23 (56.10)	
51 to 75	147 (35.1)	249 (39.1)		304 (37.72)	82 (39.81)	18 (43.90)	
76 to 100	3 (0.71)	4 (0.62)		6 (0.74)	1 (0.49)	0 (0)	
>100	00 (00)	00 (00)		0 (0)	0 (0)	0 (0)	

a – Chi^2 test, * significant at <0.05, ** significant at <0.01, * significant at <0.001, NS = p – value > 0.01**

In table 4.1.7.4 data obtained from the food frequency questionnaire has been described. Subjects are distributed in percentages as per the frequency of consumption of some selected food groups. It was observed that no subjects consumed fish and sea foods frequently. Very diminutive proportion of the study population consumed meat-poultry (1.98%), nuts- oil seeds (24.05%) and fruits (14.48%) frequently. On the contrary, pulses and legumes, leafy vegetables and sugars were consumed rather frequently by more than 55% subjects. There was no significant difference in percentage of males and females frequently consumed the selected food groups, except leafy vegetables and fruits; comparatively high percentage of female subjects frequently consumed these food groups. Age apparently didn't show any significant association with frequency in consumption of the selected food groups; except the consumption of other vegetables and readymade food items.

Table 4.1.7.4: Distribution of baseline subjects consumed particular food groups

Parameters	Male (419)	Female (637)	P – value [a]	60-69 years (809)	70-79 years (206)	≥80 years (41)	P – value [a]
Cereals/ grains	100 (100)	100 (100)	N/A	00 (00)	00 (00)	00 (00)	N/A
Pulses/ legumes	263 (62.77)	424 (66.56)	0.20 NS	535 (66.13)	128 (62.14)	24 (58.54)	0.37 NS
Leafy vegetables	291 (69.45)	404 (63.42)	0.043 *	539 (66.63)	132 (64.08)	24 (58.54)	0.47 NS
Roots/ tubers	414 (98.81)	630 (98.9)	0.88 NS	799 (98.76)	204 (99.03)	41 (100)	0.74 NS
Other vegetables	375 (89.50)	565 (88.70)	0.68 NS	718 (88.75)	191 (92.72)	31 (75.61)	0.005 **
Nuts/ oils	102 (24.34)	137 (21.51)	0.25 NS	183 (22.62)	49 (23.79)	6 (14.63)	0.43 NS
Fruits	117 (27.92)	136 (21.4)	0.014 *	191 (23.61)	54 (26.21)	9 (21.95)	0.70 NS
Fishes/ sea foods	00 (00)	00 (00)	N/A	00 (00)	00 (00)	00 (00)	N/A
Meat/ poultry	9 (2.15)	12 (1.88)	0.76 NS	17 (2.10)	3 (1.46)	1 (2.44)	0.82 NS
Milk/ milk products	340 (81.15)	517 (81.16)	0.99 NS	646 (79.85)	173 (83.98)	38 (92.38)	0.06 NS
Sugars	228 (54.42)	357 (56.04)	0.60 NS	445 (55.01)	112 (54.37)	28 (68.29)	0.23 NS
Readymade Cooked items	259 (61.81)	393 (61.70)	0.96 NS	518 (64.03)	118 (57.28)	16 (39.02)	0.001 ***

a – Chi^2 test, * significant at <0.05, ** significant at <0.01, * significant at <0.001, NS = p – value > 0.01**

4.1.8: Knowledge osteoporosis, calcium and vitamin D

Table 4.1.7.1 shares the information about knowledge acquired by the subjects regarding osteoporosis and relevant nutrients like calcium and vitamin D. About 42.70% subjects were aware of osteoporosis and vitamin D, and 48.95% subjects were aware of calcium as an important nutrient for bone health. Moreover, number of female subjects who were aware of osteoporosis and the two key nutrients to maintain healthy bone was higher (statistically significant for calcium) than male subjects. A study by Mithal A. *et al.* (2014), relevant to this discussion, documented that awareness level of osteoporosis in India is low. Small-scale surveys have reported a very poor level of awareness of osteoporosis even in the urban population i.e. only 10-15%. However, the study also has mentioned that the awareness varies widely according to the level of education and a family history of the disease.

Table 4.1.8.1: Knowledge of osteoporosis, calcium and vitamin D among the subjects

Knowledge	Male (419)	Female (637)	Total (1056)	P – value [a]
Osteoporosis	180 (42.96)	271 (42.54)	451 (42.70)	0.01 NS
Calcium	230 (54.89)	287 (45.05)	517 (48.95)	9.78 ***
Vitamin D	180 (42.96)	271 (42.54)	451 (42.70)	0.01 NS

Figures in the parenthesis denote percentage of subjects, Chi^2 test, ***significant at <0.001, NS = p – value > 0.01

4.1.9: Morbidity profile of the subjects

Table 4.1.9.1 gives us a picture of occurrence of chronic morbidities among the study population. Few noticeable morbidities like oral problems (denture problems, pyorrhea etc.), gastro intestinal problems (acidity, gas, indigestion etc.), cardio vascular problems (chest pain, high blood pressure), locomotor problems (joint pain, problems in knees, difficulties in walking etc.) and problems with central nervous system (Parkinson's, dementia etc.) were prevalent among 18.5%, 16.8%, 19.6%, 46.5% and 14.4% subjects, respectively. It was also observed that most of the chronic diseases were more prevalent among females (significant for oral problems, GI problems, locomotor problems and CVD problems) compared to males. When the subjects were classified age-wise, of all locomotor problems, CVDs, oral problems and problems with CNS frequented the prevalence most. It was also noted that oldest elderly age group included the maximum number of subject suffering from oral problems, respiratory problems, CVDs and problems with CNS, compared to the other two age groups (statistically significant).

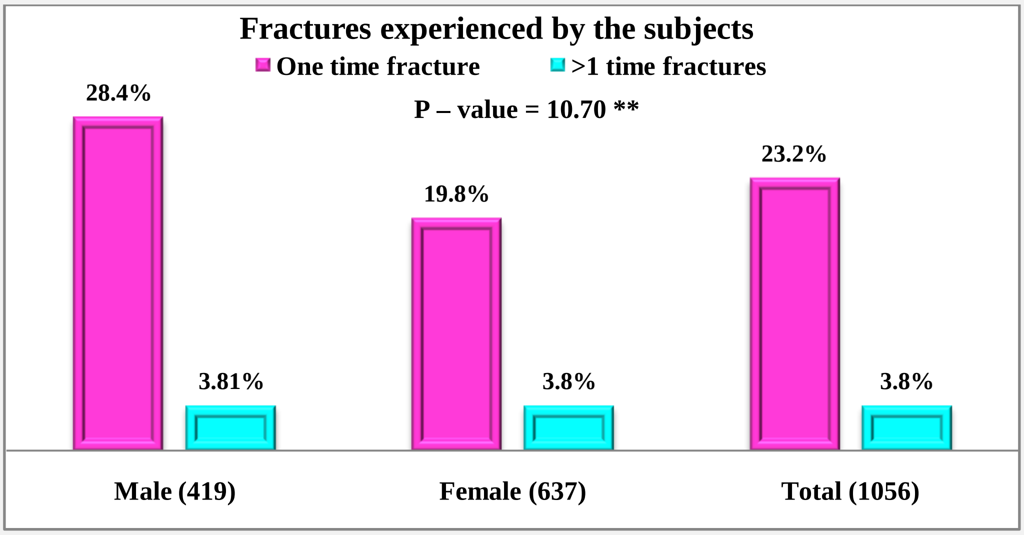
Table 4.1.9.1: Morbidity profile of the subjects

Morbidity	Male (419)	Female (637)	P – value	60-69 years (809)	70-79 years (206)	≥80 years (41)	P– value
Oral	60 (14.32)	135 (21.19)	7.93 ***	137 (16.93)	46 (22.33)	12 (29.27)	6.48 *
Respiratory	33 (7.88)	43 (6.75)	0.47 NS	47 (5.81)	23 (11.17)	6 (14.63)	10.58 **
GI	46 (10.98)	131 (20.57)	16.64 ***	138 (17.06)	33 (16.02)	6 (14.63)	0.26 NS
Hepato-biliary	7 (1.67)	8 (1.12)	0.31 NS	10 (1.24)	4 (1.94)	1 (2.44)	0.89 NS
Pancreas	9 (2.15)	9 (1.41)	0.81 NS	14 (1.73)	2 (0.97)	2 (4.88)	3.12 NS
Endocrine	28 (6.68)	49 (7.69)	0.38 NS	57 (7.05)	17 (8.25)	3 (7.32)	0.35 NS
CVD	96 (22.91)	111 (17.43)	4.81 *	136 (16.18)	53 (25.73)	18 (43.90)	24.26 ***
Genito-urinal	11 (2.63)	18 (2.83)	0.03 NS	20 (2.47)	7 (3.40)	2 (4.88)	1.25 NS
Locomotor	152 (36.28)	340 (53.38)	29.69 ***	375 (46.35)	96 (46.60)	21 (51.22)	0.37 NS
CNS	53 (12.65)	99 (15.54)	1.71 NS	99 (12.24)	44 (21.36)	9 (21.95)	13.06 **

Figures in the parenthesis denote percentage of subjects, Chi^2 test, * significant at <0.05, * significant at <0.05, ** significant at <0.01, NS = p – value > 0.01**

As depicted in the Figure 4.1.9.2, 23.2% elderly subjects experienced at least one fracture in life time, and number of males experienced fractures significantly more i.e. 28.4% than females. A very few subjects had experienced repetitive fractures i.e. 3.8% in life time. Numerous studies are available which had shown a significant association between poor BMD and fracture. One such study is i.e. a report by the Ministry of Home Affairs (2011) made a prediction that with the rapid increase in the ageing population, an explode in the numbers of fractures is expected in the next decade. Another study conducted by Marwaha RK. *et. al.* (2011) documented that vertebral fractures are common among Indians. Around 15-20% urban older adults (>50 years) evidenced at least one vertebral fracture; and also the prevalence of radiographic vertebral fractures among older adults in Delhi has been recently reported as 17.9% (18.8% male and 17.1% female.

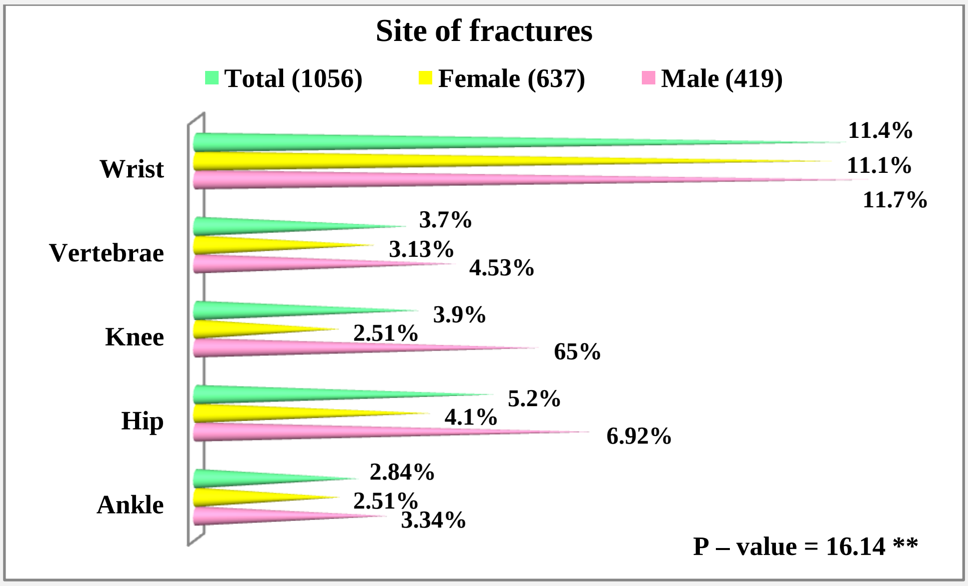
Figure 4.1.9.2: Fracture index of the baseline subjects



Chi^2 test, ** significant at <0.01

Data showed that wrist is the most common site of fracture (11.45%) for this study population followed by hip (5.11%), knee (3.88%), vertebra (3.59%) and ankle (2.84%). Females experienced wrist fractures more than male subjects (4.1.9.3).

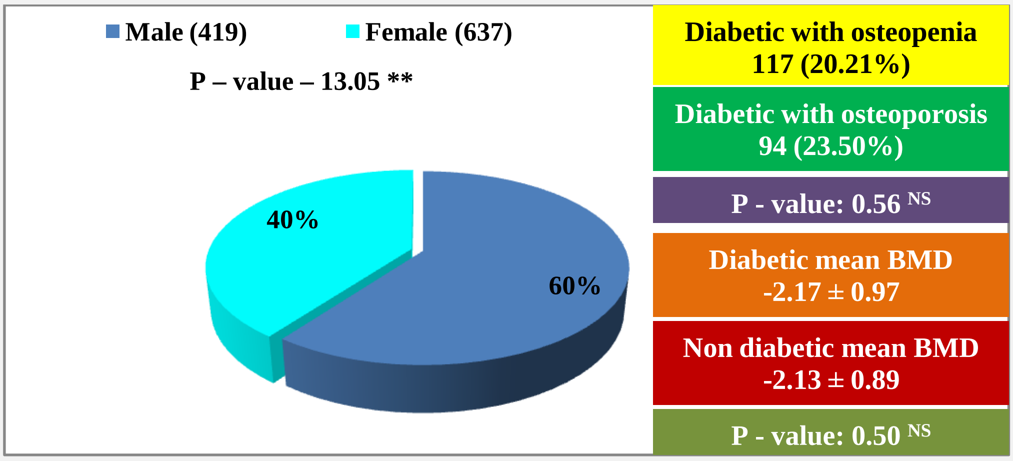
Figure 4.1.9.3: Site of fractures among the baseline elderly subjects



Chi2 test, ** significant at <0.01

Diabetes was found to be prevalent among 22.44% elderly subjects, however, it was prevalent significantly more among males (28.16%) compared to females (18.68%). When diabetes and BMD were integrated it was found that 20.21% diabetic subjects had osteopenia and 23.50% had osteoporosis (not significant). Subjects who reported diabetes had a mean BMD T – score of -2.17 ± 0.97 compared to the non-diabetics i.e. -2.13 ± 0.89 (not significant) (Figure 4.1.9.4). To find out the association between diabetes mellitus and increased fracture risk 5,994 men (aged ≥65 years) with self reported DM (T2) were gone through with their BMD assessment. After age, race, clinic site and total hip BMD was adjusted, the risk of non-vertebral fracture was found to be higher among men with diabetes compared with non-moglycaemic men (HR 1.30, 95% CI 1.09, 1.54) and the risk was further elevated in men who were on insulin (HR 2.46, 95% CI 1.69, 3.59) (Napoli N. *et. al.*, 2014).

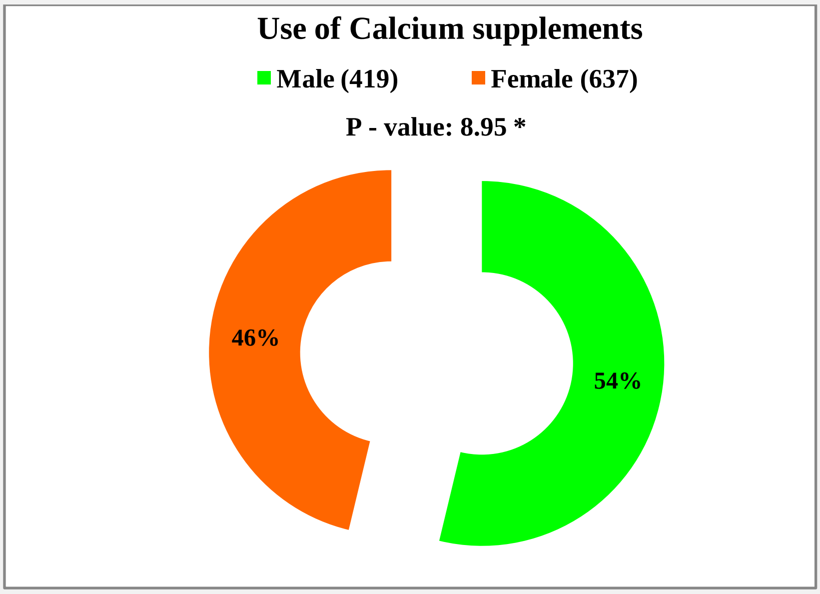
Figure 4.1.9.4: Prevalence of diabetes amongst the elderly subjects



Chi2 test, ** significant at <0.01

Data points in the diagram 4.1.9.5 are representative of percentage of subjects had a history of calcium supplementation; and it was noted that 46% males and 54% females had taken calcium supplementation at some point of time in the past. However, those subjects were not included in the second phase of the current study for not being able to under fit the inclusion criteria.

Figure 4.1.9.5: Subjects with the history of taking calcium supplementation



Chi^2 test, * significant at <0.05

4.1.10: Biophysical profile of the baseline subjects

Systolic BP and diastolic BP were assessed among the subjects and presented in this section.

Table 4.1.10.1 is representative of biophysical profile of baseline study population. Data in this table showed that the 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 diastolic SBP (86.1±10.6) and DBP (130.01±13.1). It also was noted that 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. However, there was no significant difference in systolic BP of males and females, and pre-hypertension, hypertension stage I and II were significantly more prevalent among females. Table 4.2.14 also represented the mean SBP of young elderly age group as 130.16±15.30 and mean DBP as 84.86±10.89. In the same age group only 14.96% subjects presented themselves having normal SBP; of other remarkable features 57.60% subjects having systolic pre-hypertension are mentionable here. In old elderly age group, subjects had a mean SBP of 130.27±31.16, a DBP of 84.33±11.09. Besides, 60.19% subjects had systolic pre-hypertension and 35.44% had diastolic hypertension stage I. In the oldest elderly group mean SBP of the subjects was 130.10±11.75, DBP was 84.34±10.85 and systolic and diastolic pre-hypertension was prevalent among 70.73% and 34.15% subjects. Although the number of subjects distributed in each BP category both gender-wise and age group-wise was different but nowhere the difference was statistically significant. Hypertension and osteoporosis share common aetiologies a lot. In a study Woo j. *et al.* (2009) tried and showed that SBP was positively associated with BMD among 4000 Chinese men and women of ≥65 years. Another study based on a retrospective analysis of 586 postmenopausal women with a mean age of 60.8 ±8.8 years was screened for osteopenia or osteoporosis and divided into two groups i.e. hypertensive (HT, *n*= 306) and normotensive (NT, *n* = 290). Results showed the group with femur T scores had higher age, systolic BP, duration of hypertension and duration of menopause. Moreover, the linear regression analysis showed a significant correlation between femur BMD and systolic BP, and logistic regression analysis exposed hypertension as an independent predictor of spinal osteopenia and osteoporosis (Yazici Y. *et. al*. 2011).

Table 4.1.10.1: Biophysical profile of the baseline subjects

Parameters	Male (419)	Female (637)	P – value [c]	60-69 years (809)	70-79 years (206)	≥80 years (41)	P – value [c]
Mean SBP	130.01±13.1 [a]	130.33±15.8	0.41 [NS]	130.16±15.3	130.27±31.16	130.10±11.75	0.09 [NS]
Mean DBP	86.1±10.6	83.9±10.9	3.11 **	84.86±10.89	84.33±11.09	84.34±10.85	0.61 [NS]
Systolic Blood Pressure							
Normal	51 (11.93) [b]	102 (16.01)	10.70 *	121 (14.96)	28 (13.59)	3 (7.32)	6.05 [NS]
Pre hypertensive	264 (63.1)	355 (55.73)		466 (57.60)	124 (60.19)	29 (70.73)	
Hypertensive stage I	92 (21.96)	139 (21.82)		176 (21.76)	48 (23.30)	7 (17.07)	
Hypertensive stage II	13 (3.10)	41 (6.44)		46 (5.69)	6 (2.91)	2 (4.88)	
Diastolic Blood Pressure							
Normal	70 (16.71)	148 (23.23)	10.52 *	160 (19.78)	49 (23.79)	9 (21.95)	4.67 [NS]
Pre hypertensive	141 (33.65)	229 (35.95)		293 (36.22)	63 (30.58)	14 (34.15)	
Hypertensive stage I	151 (36.04)	196 (30.77)		259 (32.09)	73 (35.44)	15 (36.59)	
Hypertensive stage II	57 (13.60)	64 (10.04)		97 (11.99)	21 (10.19)	3 (7.32)	

Figures in the parenthesis denote percentage of subjects, *a* = mean ± SD, *b* = number/ %, c – Chi^2 test, *significant at <0.05, NS: p – value > 0.01

Results highlight

- ***Total 1056 subjects with a mean age of 65.3±3.6 years were enrolled and the mean BMD T- score derived were -1.8±0.88 for males and -2.4±0.86 for females.***
- ***Mean BMD T- score of males was -1.8±0.88 and female was -2.4±0.86, respectively.***
- ***Prevalence of osteopenia was noted among 59.42% males and 47.6% females (total 52.3%). Osteoporosis was prevalent among 23.2% males and 47.6% females (total 37.9%), and only 17.42% males and 4.9% females (total 9.84%) had normal BMD.***
- ***Osteopenia was prevalent among 54.39% subjects in young elderly group, 43.69% in old elderly group and 53.66% in oldest elderly age group, respectively.***
- ***Mean per capita income (p - <0.01) and low socioeconomic status (p - <0.01) were also found to be associated with poor bone health.***
- ***Mean time spent after exercise (p - <0.05) and yoga (p - <0.01) was significantly less among the subjects with osteopenia and osteoporosis.***
- ***High mean height and low WHR was observed among the subjects with normal BMD (p - <0.001); and obesity and overweight were prevalent among 66.01% and 16.56% young elderly.***
- ***An insignificant association between nutrient intake and poor BMD was observed. 51- 75% RDA of Ca was met only by 33.7% males and 49.3% females.***
- ***23.2% experienced at least one fracture, and number of males experienced fractures significantly more (p - <0.01); and the most common site was wrist.***
- ***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.***

Concluding remarks

Male subjects intend to have better BMD T-score compared to the females of the same age, and also male participants did not show a significant decrease in mean BMD with age but females did. Prevalence of osteoporosis was significantly higher among females (<0.001) and increased with age. Daily activities, nutrient intake, lifestyle and habits, anthropometric parameters and morbidity profile could not show significant association with BMD of the chosen subjects. LIG, less knowledge of osteoporosis and related nutritional care, negligible time contributed to yoga and exercise, less active life style, osteoporotic, inadequate calcium intake coupled with high fat intake etc. accounted for general risk factors of osteoporosis.

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.

Osteoporosis is a clinical condition pigeonholed by a decrease in the density of bone, decrease in bone strength. Osteoporosis literally leads to abnormally porous, fragile and sponge like compressible bone. This skeletal disorder weakens the bone and results in frequent fractures (breaks) in the bones. Osteoporotic bone fractures are accountable for considerable pain, decreased quality of life, lost workdays, disability and long-term nursing-home care. Osteoporosis has even been linked with an increased risk of death i.e. up to 20% of women with a hip fracture die every year as an indirect result of the fracture. Thus, the target to treat osteoporosis is to prevent fractures by reducing the rate of bone loss or, preferably, by escalating bone mass density and bone strength. Besides, lifestyle changes, that stop bone loss and increase bone strength such as quitting smoking and excessive alcohol intake, regular exercising, and consuming a balanced diet that contain adequate calcium and vitamin D, careful medications etc. should be considered deliberately. With this as the background, the present study was devised to observe the effect of calcium and vitamin D supplementation on the serum calcium and vitamin D level and in improvement in bone health of osteoporotic and osteopenic elderly.

In order to present the data subjects were classified in three ways, i.e. BMD category-wise, gender-wise and age group-wise. Results have been shown under these three classifications. The results falling under this phase are presented under the following sub sections:

4.2.1 BMD and biochemical profile of the elderly subjects.
4.2.2 General information about the subjects.
4.2.3 Profile of daily activities of the subjects.
4.2.4 Habits and lifestyle profile of the subjects.
4.2.5 Anthropometric profile of the subjects.
4.2.6 Nutrient intake of the subjects.
4.2.7 Biophysical profile of the subjects.
4.2.8 Physical endurance test scores of the subjects.

4.2.1 BMD and biochemical profile of the elderly subjects

In this section pre and post interventional BMD in relation to the serum Ca and vitamin D and hemoglobin was analyzed and presented in three ways i.e. mean BMD and blood parameters according to the intervention groups and percentage prevalence of the same, BMD and blood parameters according to the gender and percentage prevalence of the same, and BMD and blood parameters according to the age and percentage prevalence of the same.

4.2.1.1 Intervention group-wise, gender-wise and age-wise mean BMD and blood parameters

Table 4.2.1.1.1 showcases data of BMD scores and biochemical parameters obtained from the four intervention groups. BMD, serum calcium, serum vitamin D and hemoglobin level of the subjects in all four groups showed insignificant difference at the baseline. Thus, the four different types of intervention were started at an indifferent level of relevant biochemical attributes to keep the impact of the treatments uninfluenced by the blood parameters. After the intervention a significant change in the mean BMD, serum Ca and vitamin D was obtained in all four groups, nevertheless at different levels. BMD T – score is inversely related to bone health. 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), respectively. Thus, the high dose along with mega dose of vitamin D_3, compared to a low dose was significantly more efficient to augment BMD, serum Ca and vitamin D within the stipulated intervention period. When the change in BMD, serum Ca and vitamin D in individual group (within the group) was accounted for, group B again confirmed the most efficient decrease in mean BMD, and most efficient increase in serum Ca and vitamin D compared to all other intervention groups. On the other hand, 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). Besides, 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). So, low dose with daily weight bearing exercise also established an evidence of improving bone health pretty much proficiently compared to a supplementation alone. Thus, two conclusions can be derived here. One, high dose of Ca and vitamin D for a medium length of time can be supplemented. Two: Low dose of Ca and vitamin D along with routine weight bearing exercises for a longer length of time can be supplemented. However, in both the cases an initial mega dose of vitamin D is recommended. It was also observed that there was no significant change in the hemoglobin level of the subjects neither in between the groups nor within the each group (from pre to post intervention). A directly proportional relationship of Ca and vitamin D supplementation with decrease in mean BMD and increase in serum Ca and vitamin D had been evidenced by a number of studies. Malhotra N. (2009) in a study conducted in northern India reported a requirement of 60,000-120,000 IU per month to achieve optimum serum vitamin D level of > 30ng/ml. Also, supplementation of vitamin D at 800 to 1000 IU/day has been recommended (10,000 IU/day: upper limit of safety) by Rizzoli R *et. al.* (2013). Similar result was documented by Verschueren SMP *et. al.* in 2011. In this RCT (2011), 113 elderly females aged over 70 years were randomly assigned either to a (whole body vibration exercise training program) WBV or a no-training group, receiving either a conventional dose (880 IU/day) or a high dose (1600 IU/day) of vitamin D3 for 6 months. In this study the documented significant improvement in hip BMD ((+ 0.75%, $p < 0.001$), serum vitamin D (+200.01%, $p < 0.001$) and dynamic muscle strength (+7.9%, $p <0.001$) in the WBV plus high vitamin D supplementation group is consistent with our findings.

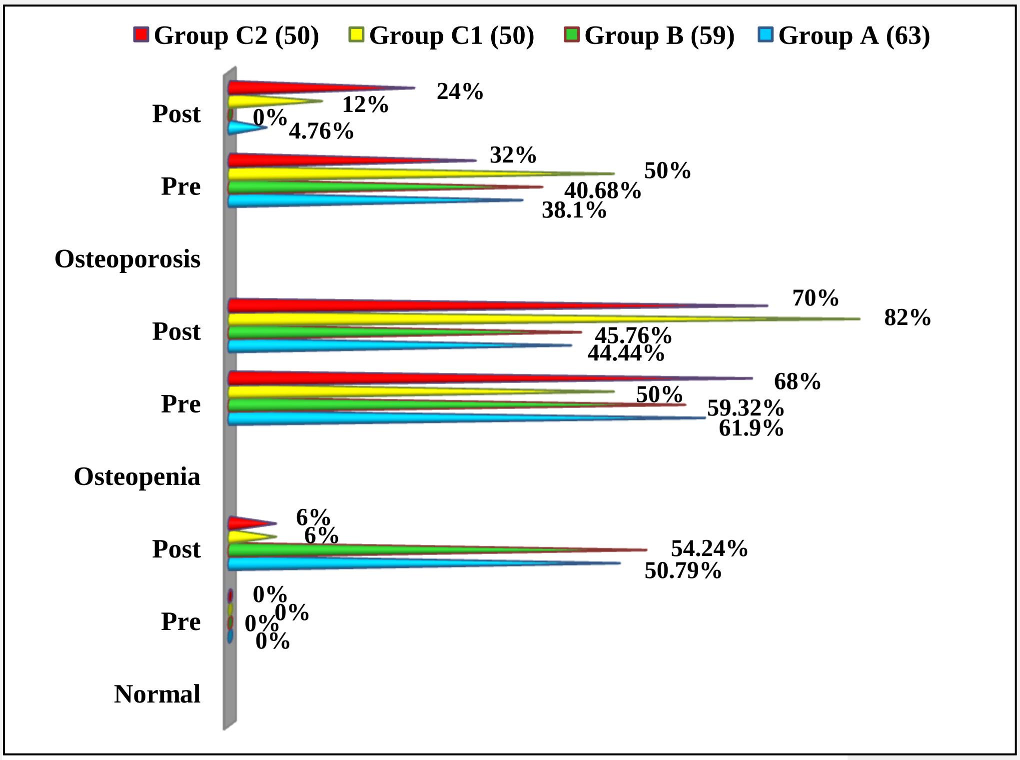
Table 4.2.1.1.1 Pre and post interventional BMD and biochemical profile of the subjects

Parameter	Group A (n=63)	Group B (n=59)	t – value [b]	Group C_1 (n=50)	Group C_2 (n=50)	t - value [b]
BMD (T - score)						
Pre	-2.36 ± 0.57 [a]	-2.39 ± 0.67	0.278 NS	-2.39 ± 0.49	-2.42 ± 0.55	0.347 NS
Post	-1.20 ± 0.72	-0.97 ± 0.44	2.13 *	-1.86 ± 0.62	-2.13 ± 0.61	0.21*
Difference	1.16 ± 0.67	1.42 ± 0.58	2.33 *	0.52 ± 0.48	0.29 ± 0.29	2.62 **
t – value [c]	13.83 ***	18.84 ***	-	7.73 ***	4.97 ***	-
Serum calcium (mg/dl)						
Pre	9.29 ± 0.68	9.62 ± 0.56	2.98 **	9.38 ± 0.63	9.39 ± 0.53	0.05 NS
Post	10.06 ± 0.55	10.21 ± 0.48	1.63 NS	9.67 ± 0.48	9.58 ± 0.50	0.90 NS
Difference	0.77 ± 0.66	0.59 ± 0.46	1.80 NS	0.29 ± 0.44	0.20 ± 0.36	1.18 NS
t - value	9.36 ***	9.88 ***	-	4.72 ***	3.94 ***	-
Serum vitamin D (ng/ml)						
Pre	16.99 ± 6.29	16.25 ± 4.57	0.74 NS	18.27 ± 4.11	16.55 ± 6.27	1.61 NS
Post	35.90 ± 8.94	42.73 ± 8.99	4.20 ***	33.13 ± 7.90	25.96 ± 16.24	2.80 **
Difference	18.91 ± 6.87	26.48 ± 8.11	5.57 ***	14.86 ± 7.89	9.41 ± 13.53	2.46 **
t - value	21.84 ***	25.08 ***	-	13.31 ***	4.91 ***	-
Hemoglobin (gm/dl)						
Pre	12.34 ± 1.07	12.29 ± 1.48	0.18 NS	12.77 ± 1.53	12.88 ± 1.84	0.33 NS
Post	12.28 ± 1.06	12.54 ± 1.1	1.33 NS	12.62 ± 1.39	12.97 ± 1.96	1.01 NS
Difference	-0.06 ± 0.60	0.24 ± 0.94	2.15 *	-0.14 ± 0.68	0.09 ± 0.58	1.84 NS
t - value	0.08 NS	1.99 NS	-	1.47 NS	0.09 NS	-

a - mean ± SD, b – median, c - minimum-maximum, d – student t test, e – paired t test, * Significant at <0.05, ** Significant at <0.01, * Significant at <0.001, NS – p value >0.05**

Scenario of poor BMD among the subjects in all four groups before and after the intervention is shown in figure 4.2.1.1.2 no significant difference was observed in the distribution of subjects in four groups with normal BMD, osteopenia and osteoporosis at the baseline. Moreover, at the baseline no subject in any group had BMD falling under normal category. However, in group A after the intervention 50.79% subjects shifted to normal BMD category and 33.34% moved out of the osteoporotic category; leaving only 4.76% in the same category (statistically significant). In group B, 54.24% subjects achieved normal BMD and among 40.68% osteoporotic subjects at baseline, no subjects stayed behind in the same category after the intervention (statistically significant). Better effectiveness of supplementation with high dose was clearly evidenced over again from the data obtained in group B. In group C_1, among 50% at the baseline, only 12% subjects remained osteoporotic after the intervention. About 38% osteoporotic subjects shifted to osteopenic and normal category (statistically significant) in the same group. In group C_2, at the post interventional time point only 6% subjects could achieve normal BMD. From the available evidences one review article compiled by Lips P *et. al.* in 2010 is just perfect to be quoted here. In the article 389 subjects (65 years) were supplemented with 700 IU vitamin D and 500 mg Ca for 6 months and had reported to reduce non-vertebral fracture risk by 50% and increased mean BMD by 1%. If the data of our study is being compared to other available studies, one inimitable component comes into the light and makes it unique is that a high dose of Ca and vitamin D along with mega dose of vitamin D for a short period is more efficient to achieve optimum results instead of giving low dose for a longer period of time. It also trim down the chances of noncompliance of supplementation and miss out or discontinuation of the same.

Figure 4.2.1.1.2 Prevalence of poor BMD among the subjects in four groups before and after the intervention



Pearson Chi^2 test, NS – not significant (all pre), Significant at <0.001 (all post)

Table 4.2.1.1.3 is indicative of the gender-wise comparisons with BMD and blood parameters in all the intervention groups. It was observed that at the baseline mean BMD T-score was significantly better among the male participants compared to the females in all the four intervention groups [A (M/F p <0.01), group C_1 (M/F p <0.01), group C_1 (M/F p <0.05) and group C_2 (M/F p <0.05)], which was then turned into an insignificant difference after the intervention. However, very grippingly female participants achieved significantly higher change in mean BMD (mean difference/reduction in T-score from pre to post) in all the groups i.e. A, B, C_1 and C_2. No significant dissimilarity was detected in mean BMD when the male participants in group A were coupled and compared with the males in group B, female participants in group A coupled with the females in group B, male participants in group C_1 coupled with males in group C_2 and females in group C_1 with females in C_2.

Mean pre serum Ca level was significantly higher among the male participants compared to the females in group A (M/F p <0.001), group C_1 (M/F p <0.01) and group C_2 (M/F p <0.01), which was later turned into an insignificant difference after the intervention. Alike BMD, female participants achieved significantly higher change in mean serum Ca (mean difference/elevation from pre to post) in all the groups i.e. A (female: 0.94 ± 0.72, male: 0.60 ± 0.54), B (female: 0.73 ± 0.49, male: 0.42 ± 0.36), C_1 (male: 0.62 ± 0.51, male: 0.08 ± 0.18) and C_2 (female: 0.26 ± 0.46, male: 0.16 ± 0.27). Anyway, means in both the genders remained in normal serum Ca category. No significant deviation was identified in mean serum Ca level when the male participants in group A were coupled and compared with the males in group B, female participants in group A coupled with the females in group B, male participants in group C_1 coupled with males in group C_2 and females in group C_1 with females in C_2.

Unlike BMD and serum Ca, pre interventional serum vitamin D level was significantly higher among the female participants compared to the male participants in group A (M/F $p < 0.001$), group C_1 (M/F $p < 0.01$) and group C_2 (M/F $p < 0.01$), which was later turned into an insignificant difference after the intervention. Although the serum vitamin D level elevated significantly in all four groups after the intervention; shunning the trend of BMD and serum Ca, mean serum vitamin D of female participants did not show any significant difference (from pre to post) from the serum vitamin D level of the male participants (except in group C_2). A significant high mean vitamin D level was identified in male participants in group B when compared with the males in group A at baseline (p- <0.05) and after the intervention (p- <0.01), and also among the female participants in group B compared to the females in group A at the baseline (p- <0.01). Contrasting group A and B, male participants in group C_1 compared to the males in group C_2 showed significant difference in the serum vitamin d level after the intervention (p- <0.001).

Mean hemoglobin level was significantly higher among the male participants compared to the females in group A (M/F $p < 0.01$), B (M/F $p < 0.01$), group C_1 (M/F $p < 0.05$) and group C_2 (M/F $p < 0.05$), which continued to remain significantly high even after the intervention. Participants accomplished no significant change in mean serum Ca (mean difference/elevation from pre to post) A, B and C_1 after the intervention. Also, no significant deviation was identified in hemoglobin level when the male participants in group A were coupled and compared with the males in group B, female participants in group A coupled with the females in group B, male participants in group C_1 coupled with males in group C_2 and females in group C_1 with females in C_2.

So, the main identified characteristics of the supplementation when correlated to gender are, firstly, male subjects in all four groups started with a better mean BMD, serum Ca and hemoglobin level. However, BMD and serum Ca level of female subjects responded efficiently to the higher dose as well as to the low dose with exercise and low dose alone, almost with the same level of significance. Secondly, high dose, low dose coupled with exercise or alone could not show any exceptionally varied efficacy on serum vitamin D level of the old elderly subjects. Thirdly, hemoglobin level is not correlated with the BMD, serum Ca and vitamin D level of the subjects. A meta-analysis can be quoted here to affirm the current findings. In the year 2009 Bischoff-Ferrari H A *et. al.* analysed 8 RCTs which included supplementation of two different doses of vitamin D_3 i.e. 700-1000 IU/day and 200-600 IU/day to 2426 subjects of 65 years. An assorted increase in serum (25(OH) D concentration i.e. <60 nmol/l Vs ≥ 60 nmol/l (P=0.005) was reported. It was also documented that the risk of fall was reduced by 19% by supplementing a high dose of vitamin D [pooled (RR) 0.81, 95% CI 0.71 to 0.92; n=1921 from seven trials)].

Table 4.2.1.1.3 Gender-wise pre and post interventional BMD and specific blood parameters of the subjects

Parameters	Group A		Group B		Group C_1		Group C_2	
	Male (n=31)	Female (n-32)	Male (n=29)	Female (n-30)	Male (n=30)	Female (n-20)	Male (n=30)	Female (n-20)
BMD (T - score)								
Pre	-2.11 ± 0.53 [a]	-2.61 ± 0.51	-2.13 ± 0.49	-2.65 ± 0.73	-2.26 ± 0.48 [a]	-2.58 ± 0.45	-2.28 ± 0.50 [a]	-2.64 ± 0.55
Post	-1.18 ± 0.68	-1.23 ± 0.76	-0.91 ± 0.36	-1.03 ± 0.51	-1.76 ± 0.70	-2.02 ± 0.44	-2.07 ± 0.69	-2.23 ± 0.46
t – value [b]	10.63 ***	10.45 ***	15.16 ***	13.72 ***	4.97 **	7.00 ***	2.49 *	6.38 **
Difference	0.94 ± 0.49	1.38 ± 0.74	1.23 ± 0.44	1.61 ± 0.64	0.50 ± 0.55	0.56 ± 0.36	0.21 ± 0.47	0.41 ± 0.28
t – value [c]	M/F pre - 3.75 **, M/F post – 0.28 [NS] M/F Diff. - 2.76 **		M/F pre - 3.13 **, M/F post – 1.09 [NS], M/F Diff. - 2.68 **		M/F pre – 2.31 *, M/F post – 1.42 [NS] M/F Diff. – 0.43 [NS]		M/F pre – 2.32 *, M/F post - 0.09 [NS] M/F Diff. – 1.63 [NS]	
	A+B (M/M) pre – 0.16 [NS], A+B (M/M) post – 1.90 [NS], A+B (F/F) pre – 0.25 [NS], A+B (F/F) post – 1.18 [NS]				C_1+ C_2 (M/M) pre – 0.15 [NS], C_1+ C_2 (M/M) post – 1.69 [NS], C_1+ C_2 (F/F) pre – 0.37 [NS], C_1+ C_2 (F/F) post – 1.50 [NS]			
Serum calcium (mg/dl)								
Pre	9.68±0.50	8.90 ± 0.62	9.73 ± 0.38	9.52 ± 0.68	9.69 ± 0.38	8.92 ± 0.66	9.63± 0.28	9.03 ± 0.62
Post	10.29 ± 0.55	9.84 ± 0.46	10.15 ± 0.44	10.28 ± 0.51	9.76 ± 0.39	9.54 ± 0.56	9.79 ± 0.38	9.28 ± 0.52
t – value [b]	6.23 ***	7.35 ***	6.30 ***	8.46 ***	2.37 *	5.38 **	3.23 **	2.50 *
Difference	0.60± 0.54	0.94 ± 0.72	0.42 ± 0.36	0.73 ± 0.49	0.08 ± 0.18	0.62 ± 0.51	0.16 ± 0.27	0.26 ± 0.46
t – value [c]	M/F pre – 5.54 ***, M/F post – 3.53 *** , M/F Diff. - 2.09 *		M/F pre – 1.44 [NS], M/F post – 1.01 [NS] M/F Diff. – 3.01 **		M/F pre – 5.20 **, M/F post – 1.64 [NS] M/F Diff. – 5.36 **		M/F pre – 4.68 **, M/F post – 4.02 **, M/F Diff. – 0.91 [NS]	
	A+B (M/M) pre – 0.39 [NS], A+B (M/M) post – 1.08 [NS], A+B (F/F) pre – 3.76 **, A+B (F/F) post – 3.53 **				C_1+ C_2 (M/M) pre – 0.68 [NS], C_1+ C_2 (M/M) post – 0.25 [NS], C_1+ C_2 (F/F) pre – 0.52 [NS], C_1+ C_2 (F/F) post – 1.51 [NS]			
Vitamin D (ng/ml)								
Pre	12.93 ± 4.52	20.92 ± 5.19	16.00 ± 4.48	16.48 ± 4.72	16.78 ± 3.76	20.50 ± 3.64	13.92 ± 4.85	20.50 ± 6.17
Post	32.63 ± 7.58	39.07 ± 9.12	42.67 ± 10.88	42.78 ± 6.89	31.09 ± 8.96	36.18 ± 4.69	19.33 ± 8.22	35.91 ± 20.08

t – value ^{b}	17.17 ***	13.99 ***	14.61 ***	23.30 ***	8.11 ***	17.11 ***	5.32 ***	3.62 **
Difference	19.70 ± 6.39	18.15 ± 7.33	26.67 ± 9.83	26.30 ± 6.18	14.31 ± 9.67	15.68 ± 4.10	5.41 ± 5.57	15.41 ± 19.02
t – value ^{c}	M/F pre – 5.50 ***, M/F post – 3.01 ** , M/F Diff. – 0.89 ^{NS}		M/F pre – 0.40 ^{NS}, M/F post – 0.04 ^{NS} , M/F Diff. – 0.17 ^{NS}		M/F pre - 3.47 **, M/F post – 2.33 ** M/F Diff. – 0.59 ^{NS}		M/F pre – 4.21 **, M/F post – 4.05 **, M/F Diff. - 2.71 **	
	A+B (M/M) pre – 2.63 *, A+B (M/M) post – 4.17 **, A+B (F/F) pre – 3.51 **, A+B (F/F) post – 1.79 ^{NS}				C_1+ C_2 (M/M) pre – 2.54 *, C_1+ C_2 (M/M) post – 5.29 ***, C_1+ C_2 (F/F) pre – 0.003 ^{NS}, C_1+ C_2 (F/F) post – 0.05 ^{NS}			
Hemoglobin (gm/dl)								
Pre	12.83 ± 1.13	11.86 ± 0.76	12.87 ± 1.46	11.74 ± 1.28	13.39 ± 1.60	11.84 ± 0.76	13.7 ± 1.83	11.7 ± 1.03
Post	12.74 ± 1.19	11.83 ± 0.66	13.18 ± 0.51	11.91 ± 1.18	13.30 ± 1.26	11.61 ± 0.86	13.97 ± 1.82	11.47 ± 0.94
t – value ^{b}	0.77 ^{NS}	0.31 ^{NS}	1.57 ^{NS}	1.20 ^{NS}	0.53 ^{NS}	2.56 **	2.39 *	3.13 **
Difference	-0.09 ± 0.68	-0.03 ± 0.51	0.31 ± 1.07	0.18 ± 0.81	-0.08 ± 0.84	-0.23 ± 0.29	0.28 ± 0.65	-0.20 ± 0.28
t – value ^{c}	M/F pre – 4.03 **, M/F post – 3.75 ** , M/F Diff. – 0.43 ^{NS}		M/F pre – 3.16 **, M/F post – 5.33 ** , M/F Diff. – 0.55 ^{NS}		M/F pre – 4.02 *, M/F post – 5.27 ** M/F Diff. - 0.75 ^{NS}		M/F pre – 4.50 **, M/F post – 5.66 **, M/F Diff. – 3.10 **	
	A+B (M/M) pre – 0.10 ^{NS}, A+B (M/M) post – 1.85 ^{NS}, A+B (F/F) pre – 0.44 ^{NS}, A+B (F/F) post – 0.35 ^{NS}				C_1+ C_2 (M/M) pre – 0.68 ^{NS}, C_1+ C_2 (M/M) post – 1.65 ^{NS}, C_1+ C_2 (F/F) pre – 0.61 ^{NS}, C_1+ C_2 (F/F) post – 0.49 ^{NS}			

a - mean ± SD, b – paired t test, c – student t test, M – male, F – female, diff. – difference, * Significant at <0.05, ** Significant at <0.01, * Significant at <0.001, NS – p value >0.05**

Data in table number 4.2.1.1.4 represents the prevalence of osteopenia and osteoporosis among the male and female subjects in all four groups both at the beginning and after the intervention. No male or female subjects with normal BMD were included in the study at the baseline. However, after the intervention 77.42% males and 46.88% females in group A, 48.28% male and 56.67% female in group B, 90.0% male and 85% female in group C_1 and only 10% male in group C_2 were able to achieve normal BMD. The other attention grabbing change that occurred was the shift of 22.58% males from osteopenia to the normal category and the shift of 50.1% females from osteoporotic to osteopenia or normal category in group A. More to the point, in group B, shift of 56.67% females from osteoporotic category to normal category evidenced that high percentage of female subjects compared to males responded efficiently to the supplementation of oral Ca and vitamin D. In group C_1 40% males and 65% females moved out of the osteoporotic category to either osteopenic or normal category. In group C_2 3.33% males and 15% females moved out of the osteoporotic category after the intervention. So, from the data it can be concluded that percentage of female subjects was more than male subjects responded efficiently to the supplementation. Availability of evidences specially executed on Ca and vitamin D supplementation and its correlation to gender is really very scanty in nature. A meta-analysis of 29 randomised trials (n=63 897) compiled by Benjamin MP *et. al.* in 2007 is favourable to be quoted here. In this report 23 trials (n=41 419, men and women of ≥50 years), reported that the treatment (1200 mg of calcium, and 800 IU of vitamin D) was associated with a reduced rate of bone loss of 0·54% (0·35–0·73; p<0·0001) at the hip and 1·19% (0·76–1·61%; p<0·0001) in the spine.

Table 4.2.1.1.4 Gender-wise pre and post interventional prevalence of poor BMD among the subjects

Groups	Normal				Osteopenia				Osteoporosis			
	Male		Female		Male		Female		Male		Female	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Group A	0	17 (54.84)	0	15 (46.88)	24 (77.42)	13 (41.94)	15 (46.58)	16 (50.0)	7 (22.58)	1 (3.23)	17 (53.13)	1 (3.13)
McNemar – value [a]	M (pre) and F (pre) Vs. M (post) and F (post) - NA				M (pre) and F (pre) Vs. M (post) and F (post) 1.23 ^{NS}				M (pre) and F (pre) Vs. M (post) and F (post) 3.13 ^{NS}			
Chi^2 value [b]	Pre M vs. F: 6.22 *, Post M vs. F: 0.41 ^{NS}											
Group B	0	14 (48.28)	0	17 (56.67)	22 (75.86)	15 (51.72)	13 (43.33)	13 (43.33)	7 (24.14)	0	17 (56.67)	0
McNemar - value	M (pre) and F (pre) Vs. M (post) and F (post) - NA				M (pre) and F (pre) Vs. M (post) and F (post) 1.83 ^{NS}				M (pre) and F (pre) Vs. M (post) and F (post) NA			
Chi^2 value	Pre M vs. F: 6.46 **, Post M vs. F:0.41 ^{NS}											
Group C_1	0	27 (90.0)	0	17 (85.0)	18 (60)	3 (10)	7 (35.0)	3 (15.0)	12 (40)	0	13 (65.0)	0
McNemar - value	M (pre) and F (pre) Vs. M (post) and F (post) - NA				M (pre) and F (pre) Vs. M (post) and F (post) 9.33 **				M (pre) and F (pre) Vs. M (post) and F (post) NA			
Chi^2 value	Pre M vs. F: 3.00 ^{NS}, Post M vs. F: 0.28 ^{NS}											
Group C_2	0	3 (10.0)	0	0	23 (76.67)	21 (70)	11 (55)	14 (70)	7 (23.33)	6 (20)	9 (45)	6 (30)
McNemar - value	M (pre) and F (pre) Vs. M (post) and F (post) - NA				M (pre) and F (pre) Vs. M (post) and F (post) 1.73 ^{NS}				M (pre) and F (pre) Vs. M (post) and F (post) 1.00 ^{NS}			
Chi^2 value	Pre M vs. F: 2.58 ^{NS}, Post M vs. F: 2.50 ^{NS}											

Figures in parenthesis denote percentages, a – McNemar test, b - Chi^2 test, M: male, F: female, * Significant at <0.05, ** Significant at <0.01, NS: p – value > 0.05

Table 4.2.1.1.5 gives a glimpse of the association that age groups share with BMD, serum Ca and vitamin D. Observations indicated an insignificant baseline disparity in BMD, serum Ca and vitamin D and hemoglobin level of the subjects distributed as young elderly and old elderly in group A, B, C_1 and C_2; and lingered onto the same even after the supplementation. No other group, yet only in group B, a significant post interventional elevation in mean serum Ca level of the young elderly subjects was noticed compared to the old elderly age group (p - <0.05). No significant dissimilarity was detected in mean BMD when the young elderly participants in group A were paired and compared with the young elderly in group B, old elderly participants in group A paired with the old elderly in group B, and young elderly participants in group C_1 paired with young elderly in group C2. Besides, mean BMD T-scores of old elderly subjects in group C_1 (-1.74 ± 0.35) reduced more significantly (p - <0.05) than the old elderly subjects in group C_2 (C_2 -2.27 ± 0.47).

Age group-wise division of the subjects revealed that both pre and post interventional serum Ca level of young elderly participants in group B significantly contrasted the serum Ca level of young elderly in group A (p - <0.05). Mean serum Ca showed no significant difference when young elderly participants in group C_1 were paired and compared with the young elderly in group C_2, old elderly participants in group C_1 paired with the old elderly in group B, young elderly participants in group C_1 paired with young elderly in group C_2 and old elderly participants in group C_1 paired with the old elderly in group C_2.

On comparison of serum vitamin D level with age groups, young elderly subjects in group B compared to the young elderly in group A could improve vitamin D level significantly more (p - <0.01) after the intervention. Parallel findings were obtained on comparison of old elderly in group B with old elderly in group A (p - <0.05). However, no significant correlation was found when young elderly and old elderly in group C_1 were compared with the young elderly and old elderly in group C_2.

Similarly, hemoglobin level also could not establish any significant association with age in any intervention group.

Thus, considering the association between age and interventional outcome the concluding remarks can be drawn as; firstly, age could not present itself as an advantage to the supplementation of varied natures considering elevation in BMD. Secondly, young elderly subjects responded to the supplementation more and efficiently to the high daily dose of Ca and vitamin D to raise serum Ca and vitamin D levels. Scientific studies focussed on gender, Ca and vitamin D are not available plenteously. In a meta-analysis conducted by Bischoff-Ferrari H A *et. al.* (2009) the effect of vitamin D in women was tested in six studies (n=1468), which had a pooled relative risk reduction of fracture up to 15% compared to 19% in men and women combined. Data on men from two trials (n=211) were limited. However, treatment duration did not modulate the effect of vitamin D significantly.

Table 4.2.1.1.5 Age-wise pre and post interventional BMD and specific blood parameters of the subjects

Parameters	Group A		Group B		Group C_1		Group C_2	
	Young elderly (n=46)	Old elderly (n=17)	Young elderly (n=49)	Old elderly (n=10)	Young elderly (n=42)	Old elderly (n=8)	Young elderly (n=36)	Old elderly (n=14)
BMD (T - score)								
Pre	-2.34 ± 0.63[a]	-2.42 ± 3.40	-2.46 ± 0.68	-2.16 ± 0.59	-2.40 ± 0.51	-2.30 ± 0.36	-2.38 ± 0.58	-2.54 ± 0.48
Post	-1.16 ± 0.75	-1.32 ± 0.63	-0.97 ± 0.41	-0.99 ± 0.66	-1.89 ± 0.66	-1.74 ± 0.35	-2.08 ± 0.66	-2.27 ± 0.47
t – value [b]	12.33 ***	6.27 **	17.63 ***	8.57 **	6.61 ***	4.96 **	3.76 *	5.46 **
Difference	1.18 ± 0.65	1.10 ± 0.73	1.49 ± 0.59	1.18 ± 0.41	0.52 ± 0.51	0.56 ± 0.32	-0.30 ± 0.47	-0.27 ± 0.19
t – value [c]	Y/O pre – 0.67 ^{NS}, Y/O post – 0.52 ^{NS} Y/O diff. – 0.74 ^{NS}		Y/O pre – 0.20 ^{NS}, Y/O post – 0.95 ^{NS}, Y/O diff. – 0.12 ^{NS}		Y/O pre – 0.67 ^{NS}, Y/O post – 0.63 ^{NS} Y/O diff. – 0.85 ^{NS}		Y/O pre – 0.42 ^{NS}, Y/O post – 0.42 ^{NS}, Y/O diff. – 0.87 ^{NS}	
	A+B (Y/Y) pre – 0.87 ^{NS}, A+B (Y/Y) post – 1.55 ^{NS}, A+B (O/O) pre – 1.85 ^{NS}, A+B (O/O) post – 1.37 ^{NS}				C_1+ C_2 (Y/Y) pre – 0.21 ^{NS}, C_1+ C_2 (Y/Y) post – 1.28 ^{NS}, C_1+ C_2 (O/O) pre – 1.28 ^{NS}, C_1+ C_2 (O/O) post – 2.79 *			
Serum calcium (mg/dl)								
Pre	9.27 ±0.70	9.33 ± 0.64	9.58 ± 0.57	9.90 ± 0.47	9.35 ± 0.65	9.54 ± 0.50	9.44 ± 0.53	9.25 ± 0.53
Post	10.0 ± 0.54	10.22 ± 0.54	10.25 ± 0.48	10.09 ± 0.54	9.68 ± 0.50	9.62 ± 0.36	9.57 ± 0.53	9.61 ± 0.42
t – value [b]	7.76 ***	5.20 **	10.53 ***	1.93 ^{NS}	5.65 **	1.34 ^{NS}	2.40 *	3.71 **
Difference	0.73 ± 0.64	0.90 ± 0.71	0.66 ± 0.44	0.18 ± 0.40	0.33 ± 0.46	0.08 ± 0.17	0.13 ± 0.34	-0.36 ± 0.36
t – value [c]	Y/O pre – 0.81 ^{NS}, Y/O post – 0.23 ^{NS}, Y/O diff. – 0.45 ^{NS}		Y/O pre – 0.34 ^{NS}, Y/O post – 0.33 ^{NS} Y/O diff. – 0.02 *****		Y/O pre – 0.56 ^{NS}, Y/O post – 0.78 ^{NS}, Y/O diff. – 0.25 ^{NS}		Y/O pre – 1.34 ^{NS}, v post – 0.84 ^{NS}, Y/O diff. – 2.08 ^{NS}	
	A+B (Y/Y) pre – 2.38 *, A+B (Y/Y) post – 2.36 ***,** A+B (O/O) pre – 2.12 *, A+B (O/O) post – 0.87				C_1+ C_2 (Y/Y) pre – 0.65 ^{NS}, C_1+ C_2 (Y/Y) post – 0.93 ^{NS}, C_1+ C_2 (O/O) pre – 1.24 ^{NS}, C_1+ C_2 (O/O) post – 0.03 ^{NS}			
Vitamin D (ng/ml)								
Pre	17.68 ± 6.35	15.13 ± 5.88	16.26 ± 4.70	15.70 ± 4.44	18.63 ± 4.09	16.38 ± 3.98	17.38 ± 6.40	14.44 ± 5.57

Post	36.85 ± 9.66	33.33 ± 6.11	43.12 ± 8.19	36.68 ± 10.28	33.50 ± 7.51	31.17 ± 10.07	28.51 ± 18.23	19.41 ± 5.87
t – value ^{b}	18.87 ***	10.53 ***	24.96 ***	7.21 **	13.61 ***	3.50 **	4.36 **	3.36 **
Difference	19.17 ± 6.89	18.20 ± 6.99	26.86 ± 7.53	20.98 ± 8.52	14.87 ± 7.08	14.79 ± 11.92	11.13 ± 15.30	4.97 ± 5.52
t – value ^{c}	Y/O pre – 0.23 ^{NS}, Y/O post – 0.25 ^{NS} , Y/O diff. – 0.68 ^{NS}		Y/O pre – 0.97 ^{NS}, Y/O post – 0.57 ^{NS}, Y/O diff. – 0.54 ^{NS}		Y/O pre – 0.27 ^{NS}, Y/O post – 0.56 ^{NS}, Y/O diff. – 0.98 ^{NS}		Y/O pre – 0.21 ^{NS}, Y/O post – 0.13 ^{NS}, Y/O diff. – 0.22 ^{NS}	
	A+B (Y/Y) pre – 1.24 ^{NS}, A+B (Y/Y) post – 3.41 **, A+B (O/O) pre – 0.49 ^{NS}, A+B (O/O) post – 2.09 *				C_1+ C_2 (Y/Y) pre – 1.04 ^{NS}, C_1+ C_2 (Y/Y) post – 1.62 ^{NS}, C_1+ C_2 (O/O) pre – 0.86 ^{NS}, C_1+ C_2 (O/O) post – 3.48 *			
Hemoglobin (gm/dl)								
Pre	12.22 ± 1.08	12.66 ± 1.00	12.19 ± 1.44	12.95 ± 1.82	12.65 ± 1.52	13.40 ± 1.50	12.92± 1.96	12.76 ± 1.57
Post	12.23 ± 1.12	12.39 ± 0.87	12.43 ± 1.17	13.08 ± 0.46	12.49 ± 1.3	13.35 ± 1.28	12.99 ± 2.08	12.91 ± 1.69
t – value ^{b}	0.22 ^{NS}	1.91 ^{NS}	1.93 ^{NS}	0.63 ^{NS}	1.46 ^{NS}	0.24 ^{NS}	0.67 ^{NS}	1.17 ^{NS}
Difference	0.02 ± 0.58	-0.28 ± 0.59	0.23 ± 0.84	0.13 ± 1.52	-0.16 ± 0.7	-0.05 ± 0.52	0.07 ± 0.62	0.15 ± 0.48
t – value ^{c}	Y/O pre – 0.22 ^{NS}, Y/O post – 0.67 ^{NS}, Y/O diff. – 0.14 ^{NS}		Y/O pre – 0.37 ^{NS}, Y/O post – 0.18 ^{NS}, Y/O diff. – 0.87 ^{NS}		Y/O pre – 0.32 ^{NS}, Y/O post – 0.20 ^{NS}, Y/O diff. – 0.74 ^{NS}		Y/O pre – 0.81 ^{NS}, Y/O post – 0.90 ^{NS}, Y/O diff. – 0.71 ^{NS}	
	A+B (M/M) pre – 0.08 ^{NS}, A+B (M/M) post – 0.81 ^{NS}, A+B (F/F) pre – 0.22 ^{NS}, A+B (F/F) post – 2.34 *				C_1+ C_2 (M/M) pre – 0.70 ^{NS}, C_1+ C_2 (M/M) post – 1.29 ^{NS}, C_1+ C_2 (F/F) pre – 0.93 ^{NS}, C_1+ C_2 (F/F) post – 0.64 ^{NS}			

a - mean ± SD, b – paired t test, c – Tukey HSD, Y – young elderly, O - old elderly, dif. – difference, * Significant at <0.05, NS – p value >0.05

Pre and post - prevalence of poor bone health according to the age of the subjects in all four groups has been showcased in table 4.2.1.1.6. No subject in young and old elderly age groups with normal BMD T – score was included in the study at the baseline. However, after the intervention 54.35% young elderly and 41.18% old elderly in group A, 53.06% young elderly and 50% old elderly in group B and only 8.33% young elderly in group C_2 were able to make an appearance in the normal BMD category. Besides, in group A 21.74% young elderly moved out of osteopenia and category and 32.61% young elderly moved out of osteoporotic to osteopenia or normal category; whereas, the interchange of BMD category was less active among the old elderly subjects i.e. 41.18% from osteoporotic to osteopenia category in group A. In group B, shift of 42.86% young elderly and 30% old elderly subjects from osteoporotic category to normal category evidenced that mean BMD T – score was improved among more number of young elderly subjects compared to the old elderly subjects. In group C_1 38.09% young elderly and 37.5% old elderly moved out of the osteoporotic category to either osteopenic or normal category. Unlike other groups, in group C_2 old 8.34% young elderly and 7.14% old elderly could move out of osteoporotic after the intervention. So, from the data above following are the two conclusions that can be made. Firstly, high dose of Ca and vitamin D received efficient response from the young elderly subjects. Secondly, Interchange of BMD category was less actively executed by the old elderly subjects. In a number of researches Ca and vitamin D have been supplemented to the elderly subjects, but finding data on such supplementation targeting specific age classification of elderly is easier said than done. Data from a meta-analysis compiled by Gielen E. *et. al.* (2011) can be referred here that has evidenced beneficial effect of Ca and vitamin D supplementation on reduction of osteoporotic fractures. In this report eight double blind randomized controlled trials reported to reduce fall up to 19% (RR 0.81, 95% CI 0.71–0.92) with a dose of at least 700 IU vitamin D per day, and a 23% reduction in fall (RR 0.77, 95% CI 0.65–0.90) with serum vitamin D concentrations of 60 nmol/L (24 ng/mL), while less than 700 IU vitamin D per day could not reduce risk of fall (RR1.10, 95% CI 0.89–1.35).

Table 4.2.1.1.6 Age-wise pre and post interventional prevalence of poor BMD among the subjects

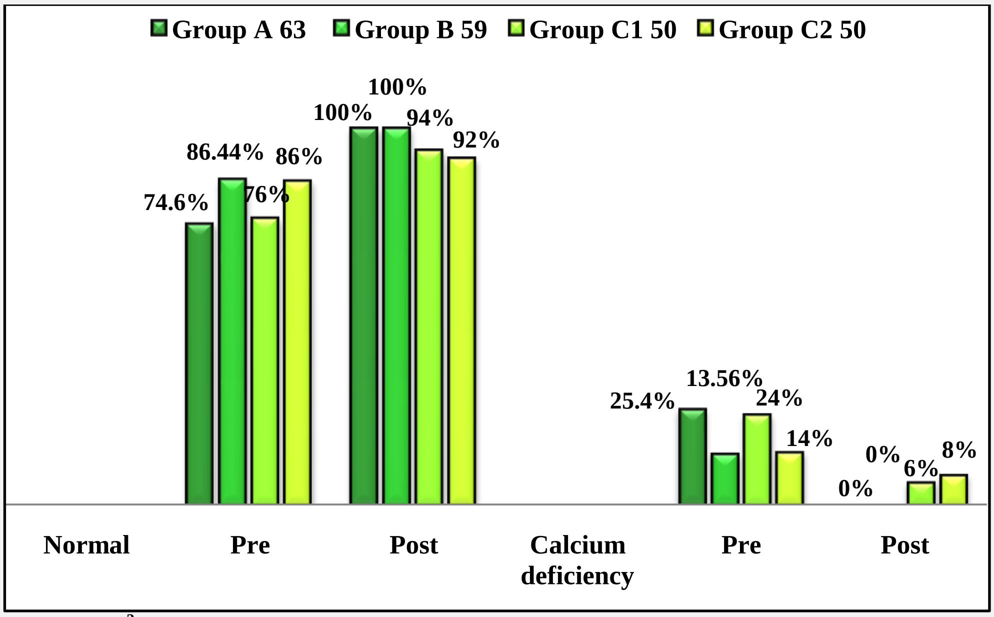
Groups	Normal				Osteopenia				Osteoporosis			
	Young elderly		Old elderly		Young elderly		Old elderly		Young elderly		Old elderly	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Group A	0	25 (54.35)	0	7 (41.18)	29 (63.04)	19 (41.30)	10 (58.82)	10 (54.82)	17 (36.96)	2 (4.35)	7 (41.18)	0
McNemar - value ^{a}	Y (pre) and O (pre) Vs. Y (post) and O (post) - NA				Y (pre) and O (pre) Vs. Y (post) and O (post) – 8.31 **				Y (pre) and O (pre) Vs. Y (post) and O (post) - 15.06 ***			
Chi^2 value ^{b}	Pre Y vs. O: 0.09 ^{NS}, Post Y vs. O: 1.99 ^{NS}											
Group B	0	26 (53.06)	0	5 (50)	28 (57.14)	23 (46.94)	7 (70)	5 (50)	21 (42.86)	0	3 (30.0)	0
McNemar - value	Y (pre) and O (pre) Vs. Y (post) and O (post) - NA				Y (pre) and O (pre) Vs. Y (post) and O (post) – 14.67 **				Y (pre) and O (pre) Vs. Y (post) and O (post) - NA			
Chi^2 value	Pre Y vs. O: 0.56 ^{NS}, Post Y vs. O: 0.03 ^{NS}											
Group C_1	0	0	0	0	20 (47.62)	36 (85.71)	5 (62.5)	8 (100)	22 (52.38)	6 (14.29)	3 (37.5)	0
McNemar - value	Y (pre) and O (pre) Vs. Y (post) and O (post) - NA				Y (pre) and O (pre) Vs. Y (post) and O (post) – 4.32 *				Y (pre) and O (pre) Vs. Y (post) and O (post) - 20.05 ***			
Chi^2 value	Pre Y vs. O: 0.08 ^{NS}, Post Y vs. O: 0.59 ^{NS}											
Group C_2	0	3 (8.33)	0	0	25 (69.44)	25 (69.44)	9 (64.29)	10 (71.43)	11 (30.56)	8 (22.22)	5 (35.71)	4 (28.57)
McNemar - value	Y (pre) and O (pre) Vs. Y (post) and O (post) - NA				Y (pre) and O (pre) Vs. Y (post) and O (post) – 5.60 *				Y (pre) and O (pre) Vs. Y (post) and O (post) - 2.40 ^{NS}			
Chi^2 value	Pre Y vs. O: 0.12 ^{NS}, c 1.34 ^{NS}											

Figures in parenthesis denote percentages, a – McNemar test, b - Chi^2 test, Y: young elderly, O: old elderly, * Significant at <0.05, ** Significant at <0.01, NS: p – value > 0.05

4.2.1.2 Intervention group-wise, gender-wise and age-wise percentage prevalence of serum calcium deficiency

Each data points in the bar graph (figure 4.2.1.2.1) represents serum calcium level that showed an insignificant difference in the number of subjects with normal serum Ca and Ca deficiency in all four groups, prior to the intervention. However, after the intervention a significant change in the serum Ca level was noticed in all four groups. In group A and B 100% subjects reallocate to the normal serum Ca level from Ca deficiency level. Unlike the other two groups in group C_1 and C_2, 6% and 8% subjects couldn't relocate to the normal serum Ca category. A number of studies suggested higher doses of Ca and vitamin D to maintain serum level of the same and to prevent osteoporosis. Such studies suggested a higher dose (1,000– 4,000 IU/day) to achieve optimum serum 25(OH) D and Ca level (Bouillon R. *et. al*., 2007; Vieth R. *et. al*. 2001).

Figure 4.2.1.2.1 Serum calcium deficiency among the subjects before and after the intervention



Pearson Chi^2 test, NS – not significant (all pre), Significant at <0.05 (all post)

Table 4.2.1.2.2 reveals the prevalence of serum Ca deficiency among the male and female subjects in all four groups both at the beginning and after the intervention. At the pre interventional phase number of male and female subjects having normal or serum vitamin D deficiency was significantly different in group

A (p - >0.01), group B (p - >0.05), group C_1 (p - >0.01) and group C_2 (p - >0.01), respectively. However, after the supplementation 100% males achieved normal serum Ca level in all four groups. Also 100% females of group A and B reached the normal serum Ca level. The observation also indicated that no significant difference in percentages of male and female subjects in normal or deficiency category in A and B. However, 15% females in group C_1 and 20% in group C_2 were left serum Ca deficient even after the intervention. Thus, the observation indicated that 100% male subjects in all groups recovered with the serum Ca deficiency after the supplementation yet not 100% females. From the very few available studies, one study conducted by Samozai MN and Kulkarni AK (2015) is been mentioned here since it presented some similar findings. The study included sixty healthy postmenopausal women on Ca and vitamin D supplementation since one month and reported that the calcium supplements were of modest significance on the serum calcium levels, however it have a significant effect on the urinary calcium levels in post-menopausal women.

Table 4.2.1.2.2 Gender-wise pre and post interventional prevalence of serum calcium deficiency among the subjects

Groups	Normal				Deficiency			
	Male		Female		Male		Female	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Group A	30 (96.77)	31 (100)	17 (53.13)	32 (100)	1 (3.23)	0	15 (46.88)	0
McNemar - value *a*	M (pre) and F (pre) Vs. M (post) and F (post) - 0.02 NS				M (pre) and F (pre) Vs. M (post) and F (post) - NA			
Chi^2 value *b*	Pre M vs. F: 15.83**, Post M vs. F: 5.52 NS							
Group B	28 (96.55)	29 (100)	23 (67.76)	30 (100)	1 (3.45)	0	7 (23.33)	0
McNemar - value	M (pre) and F (pre) Vs. M (post) and F (post) - 0.02 NS				M (pre) and F (pre) Vs. M (post) and F (post) - NA			
Chi^2 value	Pre M vs. F: 4.97 *, Post M vs. F: 5.52							
Group C_1	29 (96.67)	30 (100)	9 (45.0)	17 (85)	1 (3.33)	0	11 (55.0)	3 (15)
McNemar - value	M (pre) and F (pre) Vs. M (post) and F (post) -2.63 NS				M (pre) and F (pre) Vs. M (post) and F (post) - 0.25 NS			
Chi^2 value	Pre M vs. F: 17.56 **, Post M vs. F: 4.78 *							
Group C_2	30 (100)	30 (100)	13 (65.0)	16 (80)	0	0	7 (35.0)	4 (20)
McNemar - value	M (pre) and F (pre) Vs. M (post) and F (post) –3.67 NS				M (pre) and F (pre) Vs. M (post) and F (post) - NA			
Chi^2 value	Pre M vs. F: 12.20 **, Post M vs. F: 5.52 *							

Figure in parenthesis denotes percentages, a - McNemar test, b - Chi^2 test, M: male, F: female, * significant at <0.05, ** significant at <0.01, * Significant at <0.001, NS: p – value > 0.05**

Pre and post interventional prevalence of serum Ca deficiency among the young and old elderly subjects of all groups are being described in table 4.2.1.2.3. At the baseline young elderly subjects showed serum Ca deficiency among 21.74% in group A, 16.33% in group B, 26.19% in group C_1 and 8.33% in group C_2, respectively. Whereas, old elderly subjects showed serum Ca deficiency among 35.29% in group A, 12.50% in group C_1 and 28.57% in group C_2. After the intervention 100% young elderly in group A and B showed normal serum Ca level. In group C_1 and C_2 7.14% and 8.33% young elderly remained in the deficiency category even after the supplementation. Whereas, only 7.14% old elderly couldn't improve their serum Ca level after the intervention. However, young elderly and old elderly subjects showed no significant difference in percent prevalence of serum Ca deficiency among them. A study with similar outcome here can be talked about. However, the study has not documented the change in serum Ca levels of the experimental subjects but had provided strong evidence of fracture risk reduction as a result of Ca and vitamin D supplementation. 4957 community-dwelling northern European elderly males and females aged 66+ years supplemented 1000 mg elemental calcium and 400 IU (10 microg) vitamin D3 daily; and as an outcome fracture incidence rate was found to be reduced by 16% ($p < 0.025$) among both males and females. This study supported that supplementation of vitamin D and calcium may avert osteoporotic fractures in community-dwelling elderly people especially during winter periods (Larsen E et.al. 2004).

Table 4.2.1.2.3 Age-wise pre and post interventional prevalence of serum calcium deficiency among the subjects

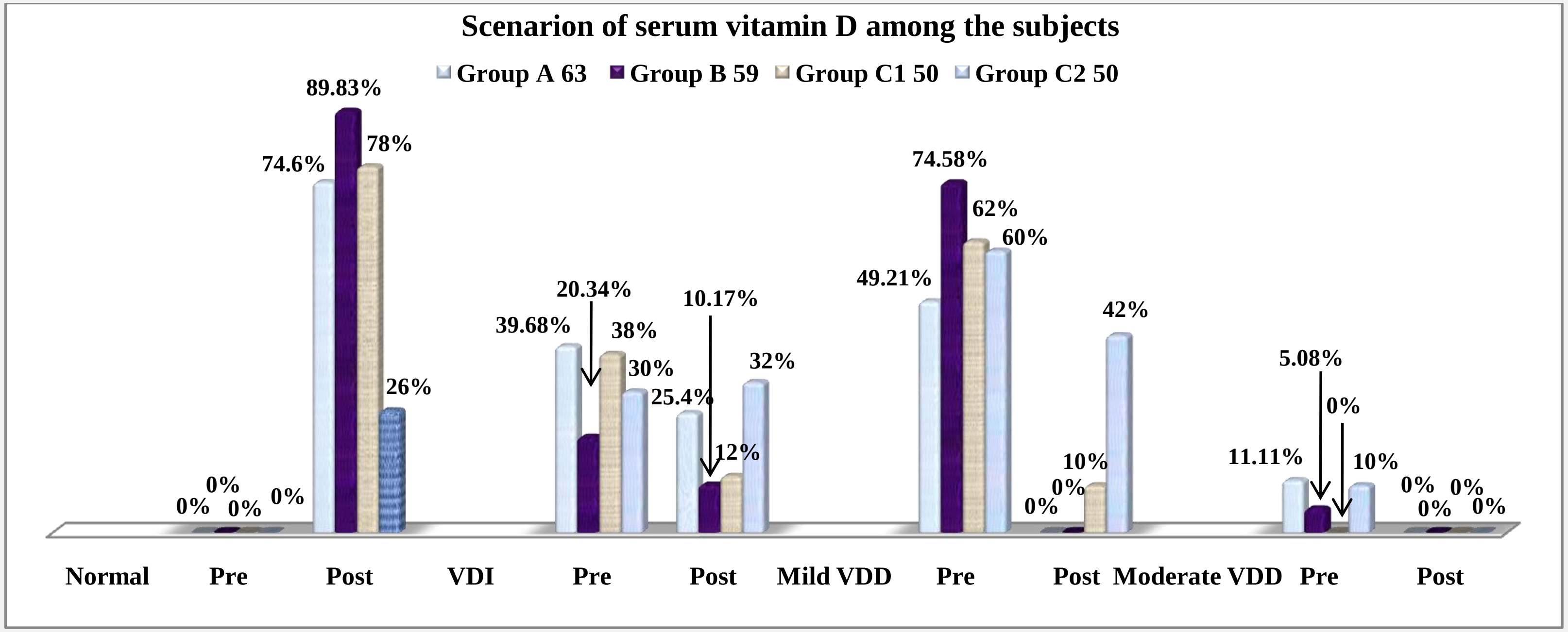
Groups	Normal				Deficiency			
	Young elderly		Old elderly		Young elderly		Old elderly	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Group A	36 (78.26)	46 (100)	11 (64.71)	17 (100)	10 (21.74)	0 (0)	6 (35.29)	0 (0)
McNemar –value [a]	Y (pre) and O (pre) Vs. Y (post) and O (post) – 6.11 [NS]				Y (pre) and O (pre) Vs. Y (post) and O (post) - NA			
Chi^2 value [b]	Pre Y vs. O: 1.20 [NS], Post Y vs. O: 0.01 ***							
Group B	41 (86.61)	49 (100)	10 (100)	10 (100)	8 (16.33)	0 (0)	0 (0)	0 (0)
McNemar -value	Y (pre) and O (pre) Vs. Y (post) and O (post) – 17.65 [NS]				Y (pre) and O (pre) Vs. Y (post) and O (post) - NA			
Chi^2 value	Pre Y vs. O: 1.88 [NS], Post Y vs. O: 0.01 ***							
Group C_1	31 (73.81)	39 (92.86)	7 (87.50)	8 (100)	11 (26.19)	3 (7.14)	1 (12.50)	0 (0)
McNemar -value	Y (pre) and O (pre) Vs. Y (post) and O (post) – 12.41 **				Y (pre) and O (pre) Vs. Y (post) and O (post) – 9.09 **			
Chi^2 value	Pre M vs. F: 0.40 [NS], Post M vs. F: 0.43 [NS]							
Group C_2	33 (91.67)	33 (91.67)	10 (71.43)	13 (92.86)	3 (8.33)	3 (8.33)	4 (28.57)	1 (7.14)
McNemar -value	Y (pre) and O (pre) Vs. Y (post) and O (post) – 7.85 **				Y (pre) and O (pre) Vs. Y (post) and O (post) – 0.25 [NS]			
Chi^2 value	Pre M vs. F:3.42 [NS], Post M vs. F: 0.01 [NS]							

Figure in parenthesis denotes percentages, a – McNemar test, b - Chi^2 test , Y: young elderly, O: old elderly, * significant at <0.05, ** significant at <0.01, NS: p – value > 0.05

4.2.1.3 Intervention group-wise, gender-wise and age-wise percentage prevalence of serum vitamin D deficiency

Figure 4.2.1.3.1 signifies the improvement in serum vitamin D level of the subjects in all four intervention groups. At the beginning no subjects had normal level of serum vitamin D in any group. However, after the intervention in group A, a statistically significant percentage i.e. 74.60% subjects attained normal level of serum vitamin D and from 49.21% moved out of mild vitamin D deficiency (VDD) category. Unlike group A, in group B 89.83% subjects achieved normal serum vitamin D level after the intervention and only 10.17% subjects stayed behind in vitamin D insufficiency (VDI) category. No subjects were left in the mild and moderate vitamin D deficiency (VDD) after the intervention (statistically significant). In groups C_1, a statistically significant percentage i.e. 78% subjects achieved normal Vitamin D level after the intervention, and also 26% and 52% subjects were moved out of VDI and mild VDD categories after the intervention. Unlike any other group, only 26% subjects in group C_2 could manage to reach the normal serum vitamin D category and 18% were still left in the mild VDD category. From the data an inference can be clearly made that subjects in group B evidenced the excellence of high dose. Although the other groups too showed certain level of improvement but determining the efficacy as an objective high daily dose of Ca and vitamin D coupled with mega dose of vitamin D for a minimum of 6 months is better efficient at its job. Based on the directions indicated by the data two more conclusions can be drawn. One, 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. Secondly, low dose for shorter tenure and without exercise is not as good as the other two doses to improve bone health of elderly. An identical low dose was supplemented to group A and group $C_{2,}$ however for 6 months to the former and for 3 months to the latter. From the other available evidences one study reported by Londhey V. in 2011 can be quoted here. A daily dose of 2000 IU of Vitamin D was recommended to avoid VDD among the Indian population. Another study from northern India reported rather high requirement of 60,000-120,000 IU per month to achieve vitamin D level of > 30ng/ml (Malhotra N. 2009).

Figure 4.2.1.3.1 Vitamin D deficiency among the subjects before and after the intervention



Pearson Chi^2 test, * Significant at <0.05 (all pre), ** Significant at <0.001(all post)

Table 4.2.1.3.2 is representative of the pre and post - prevalence of serum vitamin D deficiency among the males and females in all four groups. At the baseline males and females in group A (p - <0.001), group C1 (p - <0.01) and group C2 (p - <0.05) shared a significantly different number of subjects carrying one or the other form of vitamin D deficiency. However, the post interventional data represents no subject carrying neither moderate nor mild VDD in group A and B. However, in group C_1 16.76% males, in group C_2 66,67% males and only 5% females failed to move out of mild VDD category. Besides, 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. So, from the data it is clearly visible that higher proportion of subjects especially the female subjects achieved normal serum vitamin D level in group B, followed by group C_1, A and C_2. Thus, the data indicated that higher percentage of female subjects showed efficient change in serum vitamin D level in response to the high dose of Ca and vitamin D. A similar result producing study was done by Malhotra N. *et. al.*(2009) in New Delhi. In this study 100 adult males and females having either VDI or VDD were supplemented with 60,000 IU oral cholecalciferol/month during summer and 120,000 IU/month during winter for a period of 9 months; and it was observed that the doses safely increased vitamin D level almost near to normal.

Table 4.2.1.3.2 Gender-wise pre and post interventional prevalence of Vitamin D deficiency

Groups	Normal				VDI				Mild VDD				Moderate VDD			
	Male		Female		Male		Female		Male		Female		Male		Female	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Group A	0	20 (64.5)	0	27 (84.3)	3 (9.6)	11 (35.4)	22 (68.7)	5 (15.6)	21 (67.7)	0	10 (31.2)	0	7 (22.5)	0	0	0
McNemar - value	M (pre) and F (pre) Vs. M (post) and F (post) - NA				M (pre) and F (pre) Vs. M (post) and F (post) - 0.13 ^{NS}				M (pre) and F (pre) Vs. M (post) and F (post) - NA				M (pre) and F (pre) Vs. M (post) and F (post) - NA			
Chi^2 value	Pre M vs. F: 25.33 ***, Post M vs. F: 3.27 ^{NS}															
Group B	0	24 (82.7)	0	29 (96.6)	5 (17.2)	5 (17.2)	7 (23.3)	1 (3.3)	22 (75.8)	0	22 (73.3)	0	2 (6.9)	0	1 (3.3)	0
McNemar - value	M (pre) and F (pre) Vs. M (post) and F (post) - NA				M (pre) and F (pre) Vs. M (post) and F (post) - 1.50 ^{NS}				M (pre) and F (pre) Vs. M (post) and F (post) - NA				M (pre) and F (pre) Vs. M (post) and F (post) - NA			
Chi^2 value	Pre M vs. F: 0.64 ^{NS}, Post M vs. F: 3.12 ^{NS}															
Group C_1	0	20 (66.6)	0	19 (95)	6 (20)	5 (16.6)	13 (65)	1 (5)	24 (80)	5 (16.6)	7 (35)	0	0	0	0	0
McNemar - value	M (pre) and F (pre) Vs. M (post) and F (post) - NA				M (pre) and F (pre) Vs. M (post) and F (post) - 2.29 ^{NS}				22.04 ***				M (pre) and F (pre) Vs. M (post) and F (post) - NA			
Chi^2 value	Pre M vs. F: 10.31 **, Post M vs. F: 5.92 *															
Group C_2	4 (13.3)	4 (13.3)	11 (55)	9 (45)	21 (70)	6 (20)	9 (45)	10 (50)	5 (16.6)	20 (66.6)	0	1 (5)	0	0	0	0
McNemar - value	M (pre) and F (pre) Vs. M (post) and F (post) - 1.23 ^{NS}				M (pre) and F (pre) Vs. M (post) and F (post) - 3.23 ^{NS}				M (pre) and F (pre) Vs. M (post) and F (post) - 1.50 ^{NS}				M (pre) and F (pre) Vs. M (post) and F (post) - NA			
Chi^2 value	Pre M vs. F: 11.52 **, Post M vs. F: 18.86 **															

Figures in parenthesis denote percentages, a – McNemar test, b – Chi^2 test, M: male, F: female, * significant at <0.05, ** significant at <0.01, * significant at <0.001, NS: p – value > 0.05**

Pre and post prevalence of serum vitamin D deficiency among the young and old elderly in all the intervention groups are presented in table 4.2.8. 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 pooled post interventional normal serum vitamin D level among 70.59% in group A, 80% in group B, 62.50% in group C_1 and only 14.29% in group C_2. Besides, 7.14% young elderly in group C_1 and 38.89% in group C_2 were at hands of mild VDD after the intervention, whereas, old elderly showed 25% and 50% for the same. The distribution of young elderly and old elderly subjects in normal serum vitamin D and serum vitamin D deficiency categories evidences that percentage of young elderly subjects lying in normal or VDI category and also the number of subjects shifted from mild and moderate VDD category is greater compared to the old elderly subjects. Mentioning a study with relatively similar findings will be ingenious here. A prospective open label 3 month-study was conducted by Golombick T. and Diamond T. in 2008. The study included 23 postmenopausal young elderly women (mean age 61.2 yrs) and supplemented 1000 IU of cholecalciferol per day for one month, thereafter a maintenance dose of 500 IU of cholecalciferol per day for 2 months. The findings suggested an achievement of 86% subjects reaching Serum 25OHD3 levels >70 nmol/L.

Table 4.2.1.3.3 Age-wise pre and post interventional prevalence of Vitamin D deficiency among the subjects

Groups	Normal				VDI				Mild VDD				Moderate VDD			
	Young elderly		Old elderly		Young elderly		Old elderly		Young elderly		Old elderly		Young elderly		Old elderly	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Group A	0	35 (76.0)	0	12 (70.5)	22 (47.8)	11 (23.9)	3 (17.6)	5 (29.4)	19 (41.3)	0	12 (70.5)	0	5 (10.8)	0	2 (11.7)	0
McNemar - value	Y (pre) and O (pre) Vs. Y (post) and O (post) - NA				Y (pre) and O (pre) Vs. Y (post) and O (post) - 9.48 **				Y (pre) and O (pre) Vs. Y (post) and O (post) - NA				Y (pre) and O (pre) Vs. Y (post) and O (post) - NA			
Chi^2 value [a]	Pre Y vs. O: 5.02 ^{NS}, Post Y vs. O: 0.19 ^{NS}															
Group B	0	45 (91.8)	0	8 (80)	10 (20.4)	4 (8.1)	2 (20)	2 (20)	36 (73.4)	0	8 (80)	0	3 (6.1)	0	0	0
McNemar - value	Y (pre) and O (pre) Vs. Y (post) and O (post) - NA				Y (pre) and O (pre) Vs. Y (post) and O (post) - 4.08 *				Y (pre) and O (pre) Vs. Y (post) and O (post) - NA				Y (pre) and O (pre) Vs. Y (post) and O (post) - NA			
Chi^2 value [a]	Pre Y vs. O: 0.66 ^{NS}, Post Y vs. O F: 1.27 ^{NS}															
Group C_1	0	34 (80.9)	0	5 (62.5)	17 (40.4)	5 (11.9)	2 (25)	1 (12.5)	25 (59.5)	3 (7.1)	6 (75)	2 (25)	0	0	0	0
McNemar - value	Y (pre) and O (pre) Vs. Y (post) and O (post) - NA				Y (pre) and O (pre) Vs. Y (post) and O (post) - 12.50 **				Y (pre) and O (pre) Vs. Y (post) and O (post) - 17.93 ***				Y (pre) and O (pre) Vs. Y (post) and O (post) - NA			
Chi^2 value [a]	Pre Y vs. O: 2.43 ^{NS}, Post Y vs. O F: 0.68 ^{NS}															
Group C_2	13 (36.1)	11 (30.5)	2 (14.2)	2 (14.2)	21 (58.3)	11 (30.5)	9 (64.2)	5 (35.7)	2 (5.5)	14 (38.8)	3 (21.4)	7 (50)	0	0	0	0
McNemar - value	Y (pre) and O (pre) Vs. Y (post) and O (post) - 6.67 **				Y (pre) and O (pre) Vs. Y (post) and O (post) - 8.65 **				Y (pre) and O (pre) Vs. Y (post) and O (post) - 1.78 ^{NS}				Y (pre) and O (pre) Vs. Y (post) and O (post) - NA			
Chi^2 value [a]	Pre Y vs. O: 4.19 ^{NS}, Post Y vs. O F: 1.40 ^{NS}															

Figures in parenthesis denote percentages, a – Chi^2 test, b – McNemar test, Y: young elderly, O: old elderly, * significant at <0.001, NS: p – value > 0.05**

4.2.2 General information about the subjects

In section subjects are simply presented as per the intervention group showing their back ground information.

Insignificant distinction was found in mean age, number of male and female subjects in all four intervention groups. Also no significant difference was observed in other baseline parameters, such as marital status, type of family, religion, job, education, per capita income, socio economic status, care givers and history of fractures (table 4.2.2.1). This indicated that all the subjects in four different intervention groups had a totally similar background before the intervention was started. Sharing a common background was a chief prerequisite to keep the efficacy of different intervention on BMD independent of baseline dissimilarities.

Table 4.2.2.1 General information about the subjects before the intervention trial

Parameters	Group A (n=63)	Group B (n=59)	t – value [c]	Group C_1 (n=50)	Group C_2 (n=50)	t – value [c]
Age	66.52 ± 5.71 [a]	65.93 ± 5.38	0.58 [NS]	65.68 ± 3.48	66.92 ± 6.21	1.23 [NS]
Gender						
Male	31 (34.44) [b]	29 (32.22)	0.005 [NS]	30 (33.33)	30 (60.00)	0.003 [NS]
Female	32 (39.02)	30 (36.59)		20 (24.39)	20 (40.00)	
Marital status						
Married	49 (77.78)	43 (72.88)	0.62 [NS]	44 (80.00)	43 (80.00)	0.29 [NS]
Widow/widower	14 (22.22)	16 (27.12)		6 (12.00)	7 (14.00)	
Type of family						
Joint	33 (52.38)	25 (42.37)	1.10 [NS]	25 (50.00)	22 (44.00)	0.59 [NS]
Nuclear	30 (47.62)	34 (57.63)		25 (50.00)	28 (56.00)	
Religion						
Hindu	61 (96.83)	58 (98.31)	0.52 [NS]	49 (98.00)	48 (96)	0.58 [NS]
Others	2 (3.17)	1 (1.69)		1 (2.00)	2 (4.00)	
Job						
Working	10 (15.87)	14 (23.73)	1.08 [NS]	8 (16.00)	15 (30.00)	1.66 [NS]
Not working	53 (84.13)	45 (76.27)		42 (84.00)	35 (70.00)	
Education						
Illiterate/primary	18 (28.57)	16 (27.12)	0.27 [NS]	8 (16.00)	16 (32.00)	1.89 [NS]
School education	21 (33.33)	19 (32.20)		17 (34.00)	16 (32.00)	
Higher education	24 (38.10)	24 (40.68)		25 (50.00)	18 (36.00)	
Per capita income	7029 ± 9190	5803 ± 3501	0.95 [NS]	8446 ± 10831	9206 ± 14590	0.29 [NS]
Socio economic status (SES)						
LIG	2 (3.17)	1 (1.69)	0.38 [NS]	1 (2.00)	2 (4.00)	1.34 [NS]
MIG	59 (93.65)	56 (94.92)		47 (94.00)	48 (96.00)	
HIG	2 (3.17)	2 (3.39)		2 (4.00)	0 (0.00)	
Care givers						
Self	46 (73.02)	42 (71.19)	0.22 [NS]	38 (76.00)	42 (84.00)	0.99 [NS]
Family/spouse	17 (26.98)	17 (28.81)		12 (24.00)	8 (16.00)	
Experience of fracture						
None	45 (71.43)	34 (57.63)	1.74 [NS]	32 (64.00)	40 (80.00)	2.12 *
1 time	17 (26.98)	22 (37.29)		15 (30.0)	10 (20.00)	
2-3 times	1 (1.59)	3 (5.08)		3 (6.00)	0 (0.00)	

a- mean ± SD, b – number (%), c – student t test, * significant at <0.05, NS – p value >0.05

4.2.3 Profile of daily activities of the subjects

As depicted in the table 4.1.2 significant disparity neither at the baseline nor after the trial was found in mean time contributed to various everyday routine activities such as daily work, leisure activities, exercise, yoga, social recreation, sleep and idle 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. However, subjects in group C_1 compared to group C_2 contributed significantly more time to exercise and interestingly to sleep/rest.

Table 4.2.3.1 Profile of daily activities of the subjects before the intervention

Activities (hours)	Group A (n=63)	Group B (n=59)	P – value [b]	Group C_1 (n=50)	Group C_2 (n=50)	P – value [b]
Daily activity	3.55 ± 2.00 [a]	3.08 ± 2.10	1.42 [NS]	2.60 ± 2.03	3.21 ± 2.01	1.60 [NS]
Leisure activity	2.98 ± 1.76	3.67 ± 2.04	1.64 [NS]	3.51 ± 1.95	3.23 ± 1.93	0.79 [NS]
Exercise	0.29 ± 0.37	0.35 ± 0.33	0.82 [NS c]	0.41 ± 0.33	0.22 ± 0.26	3.20 ** [c]
Yoga	0.07 ± 0.20	0.05 ± 0.13	0.64 [NS c]	0.05 ± 0.12	0.06 ± 0.17	0.41 [NS c]
Social recreation	1.66 ± 1.46	1.48 ± 1.29	0.47 [NS]	1.52 ± 1.37	1.54 ± 1.51	0.22 [NS]
Sleep/rest	8.62 ± 1.67	8.84 ± 1.37	0.94 [NS]	8.91 ± 1.70	8.02 ± 1.73	2.69 **
Idle time	4.78 ± 2.96	4.61 ± 2.91	0.21 [NS]	4.57 ± 2.89	4.84 ± 2.63	0.68 [NS]

a - mean ± SD, b – student t test, c - Kruskal-Wallis test, ** significant at <0.01, NS – p value >0.05

4.2.4 Habits and lifestyle profile of the subjects

As portrayed in table no. 4.2.4.1 prior to the trial no significant deviation in number of subjects having similar habits and life style was detected in four intervention groups. However, merely few subjects had the habit of smoking, chewing tobacco, drinking alcohol and taking snuff which was not statistically significant. Besides, in all four intervention groups, majority of the subjects had the habit of drinking tea every day; however, the percentage of subject was not significantly different in between the groups.

Table 4.2.4.1 Habits and lifestyle profile of the subjects before the intervention

Parameters	Group A (n=63)	Group B (n=59)	Group C_1 (n=50)	Group C_2 (n=50)	P – value [a]
Smoking					
Occasionally	1 (1.59)	1 (1.69)	0.0 (0.0)	1 (2.0)	0.82 NS
Never	62 (98.41)	58 (98.31)	50 (100)	49 (98.0)	
Tobacco					
Occasionally	1 (1.59)	5 (8.47)	3 (6.00)	3 (6.0)	0.39 NS
Never	62 (98.41)	54 (91.53)	47 (94.00)	47(98.0)	
Alcohol					
Occasionally	0 (0.0)	3 (3.39)	0 (0.0)	1 (2.0)	0.31 NS
Never	63 (100)	57 (96.61)	50 (100)	49 (98.0)	
Snuff					
Occasionally	3 (4.76)	0 (0.0)	0 (0.0)	4 (8.0)	0.04 *
Never	60 (95.24)	59 (100)	50 (100)	46 (92.0)	
Tea					
Occasionally	1 (1.59)	1 (1.69)	0 (0.0)	2 (4.0)	0.79 NS
Never	5 (7.94)	3 (5.08)	3 (6.0)	2 (4.0)	
Daily	57 (90.48)	55 (93.22)	47 (94.0)	46 (92.0)	

Figures in parenthesis denote percentages, a – Chi^2 test, * significant at <0.05, NS – p value > 0.05

4.2.5 Anthropometric profile of the subjects

Anthropometric parameters such as weight, BMI, waist circumference, hip circumference and WHR as shown in the table 4.2.5.1 had an insignificant discrepancy among the groups both at the baseline and after the intervention. Moreover, in individual group no significant difference was noticed in the studied anthropometric parameters before and after the intervention; except waist circumference in group B, BMI in group A and C_2. This indicated that anthropometric parameters couldn't get the chance to interfere with the effectiveness of different interventions neither at the baseline nor during the intervention. In favour of the above findings a study by Al-Mulhim NS (2015) can be quoted here. The study showed no significant (P > 0.05) change in weight, hip circumference and BMI of 30 vitamin D deficient obese Saudi Arabian females supplemented with 50000 IU cholealciferol/week for 8 weeks.

Table 4.2.5.1 Anthropometric profile of the subjects before and after the intervention

Parameter	Group A (n=63)	Group B (n=59)	t – value [b]	Group C_1 (n=50)	Group C_2 (n=50)	t – value [b]
Weight (kg)						
Pre	66.05 ± 12.28 [a]	64.60 ± 13.93	0.61 NS	66.45 ± 15.75	66.20 ± 12.90	0.08 NS
Post	66.69 ± 12.18	65.29 ± 14.44	0.57 NS	67.06 ± 16.09	67.34 ± 12.26	0.09 NS
t – value [c]	1.58 NS	0.93 NS	-	0.68 NS	2.08 NS	-
BMI (kg/m^2)						
Pre	25.78 ± 4.78	25.75 ± 4.72	0.03 NS	26.26 ± 5.00	25.37 ± 4.70	0.91 NS
Post	25.99 ± 4.77	26.03 ± 4.99	0.04 NS	26.54 ± 5.37	25.83 ± 4.60	0.71 NS
t - value	2.09 *	0.94 NS	-	0.76 NS	2.35 *	-
Waist circumference (cm)						
Pre	66.78 ± 28.18	69.06 ± 29.78	0.43 NS	76.19 ± 29.10	72.63 ± 28.25	0.62 NS
Post	66.55 ± 28.09	68.81 ± 29.76	0.43 NS	75.09 ± 28.26	72.39 ± 27.95	0.48 NS
t - value	1.05 NS	2.34 *	-	1.31 NS	0.78 NS	-
HC circumference (cm)						
Pre	71.86 ± 27.88	74.12 ± 30.06	0.43 NS	81.10 ± 29.02	78.02 ± 28.13	0.53 NS
Post	71.26 ± 27.37	73.85 ± 29.82	0.50 NS	80.28 ± 28.41	77.07 ± 27.28	0.57 NS
t - value	1.62 NS	1.64 NS	-	1.41 NS	1.93 NS	-
WHR male (WC/HC)						
Pre	0.95 ± 0.09	0.96 ± 0.07	0.21 NS	0.96 ± 0.07	0.94 ± 0.08	1.01 NS
Post	0.96 ± 0.08	0.96 ± 0.07	0.14 NS	0.96 ± 0.06	0.96 ± 0.08	0.29 NS
t - value	1.07 NS	0.05 NS	-	0.44 NS	1.44 NS	-
WHR female						
Pre	0.88 ± 0.08	0.89 ± 0.07	0.11 NS	0.88 ± 0.08	0.89 ± 0.07	0.29 NS
Post	0.88 ± 0.08	0.89 ± 0.07	0.12 NS	0.88 ± 0.08	0.89 ± 0.07	0.34 NS
t - value	0.17 NS	1.27 NS	-	1.28 NS	0.68 NS	-

a - mean ± SD, b – student t test, c – paired t test, * Significant at 0.05, NS – p value >0.05

4.2.6 Nutrient intake of the subjects

Table 4.2.6.1 is indicative of group wise comparison of nutrient intakes at the baseline and after the supplementation. Subjects in all four intervention groups consumed significantly indifferent quantity of macro nutrients such as energy, protein, fat, and micro nutrients such as iron, calcium and vitamins such as vitamin C and B_{12} both at the beginning and after the intervention. Moreover, within the individual group no significant change in nutrient intake was perceived after the intervention. 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. Many epidemiological studies have identified null relationship between calcium supplementation and calorie intake. In one such study Lorenzen JK *et. al.* in 2007 concluded no consistent effect of calcium on appetite sensation and on energy intake at the subsequent meal.

Table 4.2.6.1 Nutrient intake of the subjects before and after the intervention

Parameter	Group A (n=63)	Group B (n=59)	t – value [b]	Group C_1 (n=50)	Group C_2 (n=50)	t – value [b]
Energy (Kcal)						
Pre	1158 ± 252[a]	1159 ± 310	0.22 NS	1186 ± 323	1169 ± 260	0.07 NS
Post	1139 ± 226	1169 ± 298	0.33 NS	1200 ± 309	1127 ± 235	1.12 NS
t – value [c]	1.80 NS	1.38 NS	-	1.72 NS	4.25 **	-
Protein (gm)						
Pre	34.98 ± 13.54	33.19 ± 9.76	0.80 NS	33.57 ± 10.14	35.48± 16.41	0.45 NS
Post	35.30 ± 11.44	33.89 ± 9.89	0.84 NS	34.20 ± 10.38	35.19 ± 13.88	0.35 NS
P - value	0.71 NS	1.78 NS	-	1.29 NS	0.86 NS	-
Fat (gm)						
Pre	39.63 ±11.10	39.59 ± 13.26	0.34 NS	40.20 ± 13.48	39.32 ± 10.03	0.18 NS
Post	38.83 ± 9.87	39.52± 12.14	0.006 NS	40.17 ± 12.36	38.51 ± 8.60	0.24 NS
t - value	0.63NS	0.60 NS	-	0.68 NS	0.87 NS	-
Iron (mg)						
Pre	10.90 ± 3.60	11.10 ± 5.70	0.41 NS	11.28 ± 6.03	11.56 ± 3.96	0.92 NS
Post	11.06 ± 3.88	11.21 ± 4.61	0.08 NS	11.34 ±4.92	11.53 ± 3.97	0.46 NS
t - value	0.24 NS	1.26 NS	-	0.03 NS	0.18 NS	-
Calcium (mg)						
Pre	584 ± 283	559 ± 276	0.63 NS	558 ± 276	573 ± 267	0.39 NS
Post	589 ± 2.88	562 ± 258	0.13 NS	562 ± 262	564 ± 267	0.27 NS
t - value	0.33 NS	0.22 NS	-	0.33 NS	0.71 NS	-
Vitamin C (mg)						
Pre	64.27 ± 42.95	59.75 ± 54.87	1.43 NS	60.02 ± 56.30	55.70 ± 41.67	0.56 NS
Post	69.78± 46.51	64.78 ± 57.54	0.56 NS	65.11 ± 60.10	56.12 ± 38.70	0.35 NS
t - value	1.03 NS	0.86 NS	-	0.74 NS	1.37 NS	-
B carotene (µ gm)						
Pre	570 ± 1228	933 ± 2014	0.06 NS	999 ± 2179	308 ± 347	0.22 NS
Post	717 ± 1632	725 ± 1701	1.07 NS	757 ± 1841	305 ± 358	0.39 NS
t - value	0.67 NS	0.66 NS	-	0.65 NS	0.93 NS	-

a - mean ± SD, b – student t test, c – paired t- test, ** significant at <0.01, NS – p value > 0.05

4.2.7 Biophysical profile of the subjects

As represented in table 4.2.7.1 biophysical parameters such as 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. When the pre systolic and pre diastolic BP was compared with the post systolic and post diastolic BP individually in each group, an insignificant difference was observed. This indicated that the supplementation in all four groups was independent of any correlation with blood pressure of the subjects at the baseline and during the intervention. A study by Margolis KL *et. al.* (2008) favours the above mentioned findings. In the study by Margolis KL *et. al.* 36282 post menopausal American women supplemented with 1000 mg calcium plus 400 IU D3/day or placebo in a double-blind fashion. Over a median follow-up time of 7 years, there was no significant difference observed in the mean change in systolic blood pressure (0.22 mm Hg; 95% CI: -0.05 to 0.49 mm Hg) and diastolic blood pressure (0.11 mm Hg; 95% CI: -0.04 to 0.27 mm Hg) between the active and placebo groups.

Table 4.2.7.1 Biophysical profile of the subjects before and after the intervention

Parameter	Group A (n=63)	Group B (n=59)	P – value [b]	Group C_1 (n=50)	Group C_2 (n=50)	P – value [b]
BP systolic						
Pre	133.62 ± 12.63 [a]	130.73 ± 13.62	121 NS	132.50 ± 14.31	135.44±11.81	1.12 NS
Post	131.98 ± 12.11	131.12 ± 14.57	0.35 NS	132.32 ± 15.66	133.04 ± 9.20	0.28 NS
t – value [c]	1.63 NS	0.38 NS	-	0.18 NS	1.41 NS	-
BP diastolic						
Pre	88.76 ± 10.67	88.14 ± 12.07	0.30 NS	90.44 ± 12.57	90.22 ± 10.55	0.09 NS
Post	90.70 ± 19.49	87.49 ± 14.96	0.01 NS	89.20 ± 15.97	93.18 ± 16.80	1.21 NS
t - value	0.74 NS	0.47 NS	-	0.74 NS	1.50 NS	-

a- mean ± SD, b – student t test, c – paired t test, NS – p value > 0.05

4.2.8 Physical endurance test scores of the subjects

Physical endurance of each subject in group C_1 was tested to rule out the additional benefit of weight bearing exercises along with supplementation. The subjects in this group were further divided in male and female; young elderly and old elderly to investigate if gender and age show specific association to physical endurance with supplementation. Before the intervention was started mean score of grip strength and standing balance was significantly better among males compared to the female subjects. However, post interventional scores connoted a significant raise in all the endurance performance (among both males and females) included in the study; 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 more in male subjects. However, an insignificant disparity in post interventional mean scores of standing balance and rise from chair was observed among males and females. Thus, from the gender-wise comparison favourable impact of exercise on physical endurance is well evidenced; but having said that gender has specific influence on certain physical endurance tasks (Table 4.2.8.1).

When the endurance test scores were compared with age, data revealed no considerable deviation between male and female at both pre and post interventional phases. However, post interventional mean scores of almost all the endurance tests increased significantly among both young and old elderly subjects. A randomized control trial of tai chi exercise performed in China by Jean Woo (2007) is comparable with our findings. The study showed an improvement in mean grip strength (14.16±2.1 to 14.83±3.3) and standing balance scores (73±6 to 71±7) among the males between 60 -75 years. Another meta-analysis carried out by El-Khoury F. *et. al.* (2013) evidenced the favourable effect of exercise on bone health of elderly. The study include 17 trials involving 4305 participants (77% women) of >60 years. The study included four categories of falls i.e. all injurious falls, falls resulting in medical care, severe injurious falls, and falls resulting in fractures. The findings identified a significant effect of exercise on all categories of fall, with pooled estimates of the rate ratios of 0.63 (95% confidence interval 0.51 to 0.77, 10 trials). The study also documented that the rate of falls leading to medical care was reduced significantly.

Table 4.2.8.1 Physical endurance among the subjects in group C_1 before and after the intervention

Parameters	Male (n=30)	Female (n-20)	t – value [b]	Young elderly (n=42)	Old elderly (n=8)	t – value [c]
Grip strength						
Pre	15.84 ± 4.86 [a]	11.73 ± 4.18	4.53 **	14.2 ± 5.22	14.1 ± 3.84	0.04 NS
Post	18.03 ± 5.34	12.65 ± 4.50	3.70 **	15.7 ± 5.95	16.6 ± 3.83	0.39 NS
Difference	2.20 ± 1.70	0.93 ± 0.69	5.00 **	1.53 ± 1.48	2.49 ± 1.51	1.66 NS
P – value [d]	7.08 ***	5.96 ***		6.71 ***	4.65 **	
Standing balance						
Pre	2.10 ± 0.71	3.00 ± 0.65	4.53 **	2.57 ± 0.77	1.88 ± 0.83	2.31 *
Post	3.33 ± 0.76	3.35 ± 0.67	0.07 NS	3.40 ± 0.70	3.00 ± 0.76	1.48 NS
Difference	1.23 ± 0.68	0.35 ± 0.49	5.0 ***	0.83 ± 0.73	1.13 ± 0.83	1.01 NS
P – value	9.95 ***	3.19 **		7.40 ***	3.81 **	
Walking speed						
Pre	4.59 ± 1.18	4.66 ± 0.85	0.21 NS	4.71 ± 1.04	4.12 ± 1.05	1.48 NS
Post	5.00 ± 1.18	4.27 ± 0.95	2.29 *	4.73 ± 1.19	4.58 ± 0.91	0.34 NS
Difference	0.40 ± 0.72	-0.39 ± 0.25	4.71 **	0.02 ± 0.72	0.46 ± 0.38	1.66 NS
P – value	3.05 **	7.06 ***		0.13 NS	3.42 **	
Rise from chair						
Pre	13.19 ± 3.38	13.88 ± 2.16	0.79 NS	13.6 ± 2.64	12.9 ± 4.45	0.56 NS
Post	14.20 ± 2.74	13.50 ± 2.53	0.91 NS	13.89 ± 2.56	14.06 ± 3.29	0.16 NS
Difference	12.79 ± 3.37	14.27 ± 2.11	1.73 NS	13.6 ± 2.65	12.5 ± 4.53	0.93 NS
P – value	4.75 ***	1.82 NS		1.68 NS	2.43 *	

a - mean ± SD, b - student t test, c - Tukey HSD test, d – paired t-test, * significant at <0.05, ** significant at <0.01, * significant at <0.001, NS: p – value > 0.05**

Results highlight

- ***Insignificant distinction was found in the general baseline information, SES, daily routine activities, anthropometric indices, blood pressure, dietary intake and chronic illnesses among the groups both at pre and post interventional time point.***
- ***Group B achieved the upmost significant decreased in mean BMD T-score (-0.97 ± 0.44), highest 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.***
- ***After the intervention 50.79% in group A, 54.24% in group B, 6% in group C_1 and 6% subjects in group C_2 shifted to normal BMD category.***
- ***In group A 74.60% subjects, in group B 89.83%, in groups C_1 78% and in group C_2 26% attained normal serum vitamin D level after the intervention.***
- ***In group A 84.38% females compared to 64.52% males achieved normal serum vitamin D level. 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 after the intervention.***
- ***Young elderly subjects responded more efficiently to the high daily dose of Ca and vitamin D to raise serum Ca and vitamin D levels.***
- ***High dose, low dose coupled with exercise or alone could not show any exceptionally varied efficacy on serum vitamin D level of the old elderly subjects.***
- ***Post interventional scores connoted a significant raise in all the endurance performance (among both males and females) included in the study; 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 more in male subjects.***

- ***Thus, the observation indicated that Group B independent of gender and age achieved the upmost significant decreased in mean BMD T-scores and increase in serum vitamin D followed by Group C_1. Group B also showed the highest percentage shift of subjects from vitamin D deficiency to normal level, followed by Group C_1.***
- ***high dose brought the highest number of subjects to normal vitamin D category, 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***

Concluding remarks

Subjects in all four intervention groups shared similar background. Also, significant disparity neither at the baseline nor after the trial was found in anthropometric parameters, nutrient intake, blood pressure and daily routine activities of the subjects in all groups. Interventional outcome showed that female participants achieved significantly higher change in mean BMD serum vitamin D level (reduction in T-score from pre to post) in all groups. Gender-wise comparison showed a favourable impact of exercise on physical endurance is well evidenced; but having said that gender has specific influence on specific physical endurance tasks. Besides, young elderly subjects responded more efficiently to the high daily dose of Ca and vitamin D to raise serum Ca and vitamin D levels. High dose along with mega dose of vitamin D_3, compared to a low dose was significantly more efficient to augment BMD, serum Ca and vitamin D within the stipulated intervention period. However, in both the cases an initial mega dose of vitamin D is recommended.

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.

- Dietary calcium intake was extremely poor among the elderly population and this is a serious matter of concern.

- 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.
- The hypothesis and the specific objectives of the study were achieved satisfactorily.