CHAPTER 1
INTRODUCTION

For decades now, India has been fighting a losing battle on eradicating communicable and infectious diseases which has posed a severe burden on the country's economic growth. Sadly enough, introduction of lifestyle and age related diseases as a fraction of non-communicable diseases have added to its woes. Non-communicable diseases consist 42 percent of all deaths in India and its 20 percent is contributed by injuries and ill-defined causes. Interestingly the majority of ill-defined causes are related to old age. If the spotlight is being put on the latter, it is discernible that senility (5.1 percent- which is concentrated at ages 70 and higher), unintentional injuries: 4.9 percent, and ill-define conditions (4.8 percent) etc. are strong contributors to old age related infirmities (Chauhan LS., 2011). So, the question that arises here is why would age related ailments alone give a skewed shape to ubiquitous non-communicable diseases? Conceivably, the escalating numbers of geriatric population and changing lifestyles with urbanization are putting a pressure on environmental as well as on nutritional requirements, which is resulting in nutritional deficiencies and eventually contributing to non-communicable diseases.

Ostensibly, in the context of non-communicable diseases, the rising number of elderly population is an affair of apprehension, but how? Globally, the share of people aged over 60 years has ascended from 8 percent of the world population (200 million people) in 1950 to around 11 percent (760 million) in 2011and is estimated to show a dramatic increase of up to 22 percent (2 billion) by the year 2050 (Beard J. *et. al.*, 2012). The altering fashion in age composition of the population over time is way faster in developing countries. As a developing country, India also has witnessed a steady and progressive rise in both the number and proportion of its elderly population (aged 60 years or above) over the last decade. The size of the elderly population has grown from 12.1 million in 1901 to approximately 77 million in Census 2001 and some projections expect the number to rise approximately to 140 million by 2021(Situation Analysis of The Elderly in India, CSO, Ministry of S & PI, Govt. of India, 2011). This trend of global ageing in developed and developing countries is alike, and is not only

bringing a crisis in socio-economic status (SES), nutrition and health of elderly population, but it is also one of the most amenably significant risks to global prosperity in the decades ahead because of its potentially profound economic, social, nutritional and health implications. With rising numbers of elderly people of late, old age related infirmities have left their footprint remarkably on the health and quality of life. A thorough review of literature can help us apprehend what the impact of senescence on the global and Indian scenario could be like. The process of senescence is characterised by both mental and physical changes; with mental changes associated with depression, fear, mental ailments, and an overall reduced cognitive ability. According to a World Health Organization (WHO) fact sheet that was published in April 2016, globally more than 20 percent of adults aged more than 60 years suffer from a mental or a neuropsychiatric disorder (like mood disorder, cognitive impairment, dementia, Alzheimer's disease etc.) and in India depression is prevalent in approximately 13 and 25 percent of elderly people (Barua A. *et. al.,* 2011). Physical changes are primarily infested as musculoskeletal, dental, digestive, visual and auditory problems to name a few. Amongst all physical changes, musculoskeletal problems pose the biggest threat. Indeed, 9.6 percent men and 18 percent women aged over 60 years suffer from symptomatic osteoarthritis and strikingly, more than 200 million senescent people have been diagnosed to be osteoporotic worldwide (International Osteoporosis Foundation, 2014).

Osteoporosis is a musculoskeletal disease which develops silently and can wreak havoc if not diagnosed on time and medicated for. Evidences indicate that osteoporosis is a leading cause of morbidity affecting elderly populations of both the sexes in most part of the world (Malhotra N., Mithal A., 2008 and Ojo F. and Edwards BJ., 2003). In the European Union alone, 22 million women and 5.5 million men had osteoporosis in 2010 (Svedbom A.*et. al.,* 2013). In the United States, 8 million women and 1-2 million men were affected by osteoporosis in 2010 (Wade SW. *et. al.,* 2014; Willson T. *et. al.,* 2015), while in Latin America vertebral osteopenia was prevalent among 45.5-49.7 percent women over 50 years of age, vertebral osteoporosis was prevalent among 12.1-17.6 percent; femoral neck osteopenia was prevalent among 46-57.2 percent and femoral neck osteoporosis among 7.9-22 percent women (Morales-Torres J. *et. al*., 2004). In Africa, Egypt was affected by postmenopausal osteopenia by 53.9% and

postmenopausal osteoporosis by 28.4% (Mohy Taha MD. 2011). In Oceania, Australia and New Zealand reported osteoporosis to be prevalent in 2.2 million and 84,000 people, respectively (Sambrook PN. *et. al.,* 2002; Osteoporosis New Zealand Inc. 2007). In Asia, osteoporosis went greatly under diagnosed and undertreated, even in the high-risk patients with a history of fracture(s). More than 70 million Chinese people aged over 50 years were diagnosed with osteoporosis (China Health Promotion Foundation, 2008). The scenario in India has not been better either as deciphered from the normative Bone Mass Density (BMD) data that was made available recently. Talking about numbers in 2003, the Osteoporosis Society of India had estimated 26 million people to be suffering from osteoporosis, with numbers expected to rise up to 36 million by 2013 (Mithal A. *et. al*. 2012). Females are at a higher risk to males in developing osteoporosis. It was estimated that worldwide osteoporosis affected approximately one-tenth of the women aged 60 years, one-fifth of the women aged 70 years, two-fifths of the women aged 80 years and two-thirds of the women aged 90 years, respectively (Kanis JA, 2007). Sources also revealed that 2- to 3-fold rise in hip fracture incidence have been observed almost in all Asian countries during the past 30 years (Mithal A. *et. al.* 2013). Amidst this world trend, women of India aged 30-60 years, especially from the low income groups, encountered a very high prevalence of osteopenia (52%) and osteoporosis (29%) (Shatrugna V. *et.al.* 2005). Osteoporosis makes post menopausal women a vulnerable segment, there by earning a scope of receiving a special and urgent attention by the health care system. Several factors attribute to an increased susceptibility to osteoporosis, for example lower peak bone mass, loss of ovarian function, and reduced oestrogen synthesis following menopause etc. Being the most common chronic disease, osteoporosis makes bones more porous and fragile and greatly increases the risk of suffering a fracture. People suffering from this serious yet mostly preventable damage frequently experience a severe pain, bone fracture, long-term disability and even early death. As the clinical outcome of osteoporosis is bone fracture, a huge attention has always been given to the identification of patients at high risk of fracture in osteoporotic condition. Worldwide, osteoporosis causes a fracture every 3 seconds resulting in more than 8.9 million fractures annually (Johnell O. and Kanis JA., 2006), and estimates project that by the year 2050, worldwide incidence of hip fracture in men will

increase by 310 percent and 240 percent in women, compared to rates in 1990 (Gullberg B. *et. al.*1997). A kin to osteoporosis, females are intended to experience osteoporotic fractures more compared to males. Worldwide, 1 in 3 women over the age 50 years experienced osteoporotic fractures, compared to 1 in 5 men of the same age (www.iofbonehealth.org, 2014; Kanis JA. *et. al.*, 2000). Largely, 61% of global osteoporotic fractures occur in women, with a female-to-male ratio of 6:1 (Johnell O. and Kanis JA., 2005). In India the magnitude of osteoporotic fractures is similar to the prevalence of osteoporosis across the country demarcated by an increased incidence of hip fracture ratios (Khadilkar VA. and Mandlik MR., 2015; Damodaran P. *et. al.* 2000). Surprisingly, there is no data available on specific or projected number of osteoporotic fractures in India which is a big impediment towards influencing government policies. If the global picture of osteoporosis and fractures induced by it are so enormous, it is not surprising to estimate its colossal impact on the economy of any nation. The burden of osteoporosis and related morbidities to the health systems, economies and society is huge and continuously increasing. The EU spends 37 billion euros/year in healthcare costs related to osteoporosis, and the USA spends an estimated 19 billion USD annually for the same (www.iofbonehealth.org, 2014). In India the prosthesis cost for surgical treatment in government hospitals is approximately 150 USD), and in private hospitals the cost is about 2500-3000 USD (Mithal A. *et. al.* 2009). Such situation places a large economic burden on the healthcare system due to costs of treatment, long-term disability, and loss of productivity in the working population.

Thus, osteoporosis is a major public health problem across the world and like every other problem; it also is influenced by a few factors. Low calcium intake coupled with an extensive prevalence of vitamin D deficiency, inactivity, increasing longevity, early menopause, lack of diagnostic facilities, sex inequality, genetic predisposition and poor knowledge of bone health care are the major fallacies contributes to the high incidence of osteoporosis. Optimum bone health may be achieved by crafting an atmosphere to reach peak bone mass during adolescence in the first place followed by safeguarding of healthy bone all through the life, and finally preventing postmenopausal bone loss. All of the above measures are majorly backed up by nutrition and lifestyle. A right combination of nutrients can help to prevent and manage osteoporosis and related

musculoskeletal disorders by supporting in the fabrication and safeguarding of bone. On the contrary, if the right nutrients are unavailable there is a greater risk for bone and joint diseases. Two such nutrients are calcium and vitamin D. Calcium (Ca) is the major building-block of bone tissue (the skeleton houses 99% of the body's calcium stores) and vitamin D is the key to absorb calcium – the two go hand in hand. A lot of evidences have favoured the fact that calcium and vitamin D play an important role in osteoporosis. A positive association between low bone mass density and poor dietary intake of Calcium and vitamin D has been well documented (Liu H, 2008). Resident Indians have a lower BMD in comparison to residents of developed countries across the world and as a possible cause, inadequate nutrition maybe blamed for. Between 1984 and 1987, the incidence of hip fracture has shown some indications of stabilization and a recession is reported in the incidence of hip fracture in cities like Rochester, Minnesota. Also in Hong Kong, a pause has been reported in incidence of hip fracture from 2001 to 2006. The possible reasons for the decline in hip fracture incidence had been assumed as socio-economical changes, increase in body mass index and prompt diagnosis and treatment of osteoporosis (Mithal A., *et. al.,* 2014). On the contrary, in 2003 a highly conservative estimate was presented by a group of experts that 26 million Indians suffered from osteoporosis, and this number is expected to reach 36 million by 2013 (Osteoporosis Society of India, 2003). Although India is a sun-rich country, deficiency of vitamin D is prevalent in almost all age groups. Vitamin D deficiency (VDD) was considered to be rare in India till the early 1990s (Hodgkin P. *et. al.* 1973). Till the year 2000, no systematic study was available which directly assessed body vitamin D status of Indians (Goswami R. *et. al.,* 2000). Then subsequently, a number of studies were conducted in different parts of the country and had documented a widespread prevalence of VDD in all age groups and in both the genders residing in rural or urban areas (Arya V. *et. al.,* 2004; Sachan A. *et. al.,* 2005; Harinarayan CV. *et. al.,* 2007; Lips P. *et. al.,* 2010). Another study carried out amongst elderly (58.0 ± 9.5 years) showed prevalence of VDD as 91.2% and Vitamin D insufficiency as 6.8% (Marwaha RK, *et. al*., 2011). Some of the reasons for such a steady rise in hypovitaminosis D are stated as avoidance of sunlight exposure due to socio-cultural reasons, poor dietary calcium and vitamin D intake, pollution, and higher levels of 25(OH)-D-24-hydroxylase enzyme in

Asian Indians (Khadilkar AV, 2010). In excess of the enzyme 25(OH)-D-24-hydroxylase in the inner mitochondrial membrane of the renal tubules of the kidneys and intestine, excess catabolism of calcitriol [1α,25(OH)2 vitamin D3] takes place and excreted in the bile which leads to vitamin D deficiency. Moreover, several studies have reported that Indian diets are inefficient to meet the recommended dietary allowances (600 mg/d of calcium for adult women) recommended by the Indian Council of Medical Research (ICMR, 2009). Poor nutritional status is also considered to be a significant risk factor for osteoporosis. Body weight less than 60 kg and height less than 155 cm may significantly increase the risk of developing osteoporosis among women (Keramat A *et. al.*, 2008). In the past, nutritional scientists have tried Ca and vitamin D supplementations to improve osteoporosis and have demonstrated it to work well (Shea B *et. al*., 2002; Pfeifer M *et. al.*, 2000; Chapuy MC. *et. al.*, 2002). In Indian women too, calcium and vitamin D supplementation has been one of the most common first-line therapies used till date (Khadilkar AV. *et. al.*, 2015).

Apart from insufficient intake of Ca and vitamin D, lack of physical activity is considered to be another contributing factor to osteoporosis. Indeed, lack of regular physical exercise is associated with lower BMD (Marwaha RK. *et. al.*, 2011; Agrawal T *et. al.*, 2013). Exercise plays an important role in building and maintaining the bone strength. Physical exercise is capable of preventing bone loss among elderly by promoting mobility, agility and muscle strength (Kuttikat A. *et. al.*, 2004).

Other than Ca and vitamin D as a contributing factor, hemoglobin have started occupying an imperative space in the picture of osteoporosis. For hemoglobin and osteoporosis, few studies abroad had evidenced that the chronic iron deficiency is an emerging risk factor for osteoporosis (Toxqui L. and Vaquero PM., 2015; Korkmaz U. *et. al.*, 2012). Another study showed cortical bone loss is associated with hemoglobin levels and women with lower hemoglobin levels demonstrated a higher bone loss than male counterparts (Cesari M. *et. al.*, 2005).

Osteoporosis patients have an increased mortality rate due to the complications of fracture which are associated with a reduced health-related quality of life. It is preventable and treatable with early diagnosis. Regrettably, it is often undiagnosed until a fracture occurs. Hence, an increasing number of people should be screened more frequently for this debilitating disorder. Measuring bone

mass density (BMD) is the most effective measurement of diagnosing osteoporosis which can only be addressed through an effective public health system. Major gaps still remain in the diagnosis, management and treatment of osteoporosis, and therefore there is a clear need for more structured research in this area.

RATIONALE

In India, with the rapidly increasing elderly population calcium and vitamin D deficiency osteoporosis has become one of the most common nutritional deficiencies and a foremost cause of morbidity. A multi strategic preventive and treating measure is needed to face the challenge. Elderly bone health and its maintenance involves a number of indicators to be handled carefully.

One such indicator is calcium (Ca) and vitamin D_3 supplementation. In old age a very high intake of Ca and vitamin D is required to fulfil the need and often the insufficient intake leads to bone mineral loss and development of osteoporosis; and the condition ultimately leaves elderly individual prone to fractures. In some part of our country, the prevalence of Ca, vitamin D deficiency and osteoporosis has been documented very high i.e. 1 out of 3 females and 1 out of 8 males; but neither the exact numbers are available (IOF; outlookindia, 2004) nor we have sufficient evidence on the correlation of poor BMD with dietary Ca and vitamin D intake among the geriatric population. Very often different types of doses are prescribed by the physicians to treat low BMD but without correlating to the serum vitamin D and calcium levels. Also there isn't sufficient evidence on efficacy trials of Ca and vitamin D doses on low BMD, serum Ca, serum vitamin D insufficiency (VDI) and deficiency (VDD) among the Indian elderly. Restoring the loss of Ca and vitamin D which has already been taken place can be the first step, then prevention of further bone loss and rebuild the BMD. This strategy may include supplementation of a high weekly dose of vitamin D for first two months to restore the loss and boost up the absorption of further regular small doses of Ca and vitamin D. The daily small doses are to maintain the optimum level of Ca and vitamin D in the blood to increase BMD and prevent further loss of bone mass. Impact of high doses of vitamin D_3 on bone health and serum vitamin D levels needs to be

investigated. Such evidence will surely be of great use to formulate national health care policies for older person.

Another indicator is dietary habits. When bone health and dietary habits are taken into consideration, it has been observed that no standardized data is available on frequency of vitamin D and calcium rich food consumption and Calcium content of traditional diet comprises of locally produced and available food stuff. It is important to explore the availability of dietary Ca and vitamin D of a particular community and prevalence of low BMD among the population. This will help to analyze the flaws in dietary habits practiced by a particular community and intervene with the required preventive and treating measures. It will also provide some evidence to revise the recommended daily allowances (RDA) and National nutritional polices for elderly population.

To bring a twist in the traditional way to prevent osteoporosis i.e. medication, a knowledge based intervention could be tried. Knowledge and awareness regarding age and gender as a risk factor for poor BMD, role of dietary calcium and vitamin D in bone health, importance of physical activity to maintain bone health etc. are the key points to formulate a knowledge based intervention to prevent bone health deterioration at the pre-geriatric age. It may influence the elderly population to bring some changes in life style, dietary and health care practices.

Apart from Ca and vitamin D, also hemoglobin is now interestingly identified as an important risk factor for osteoporosis. Several studies abroad have shown that the chronic iron deficiency is an emerging risk factor for osteoporosis. But in India such data is not available. Thus, an integration of hemoglobin status and BMD of elderly may give an indication whether poor hemoglobin status is a risk factor for poor BMD among Indian elderly.

In India it has been observed that the cost of hospitalization, treatment, rehabilitation and long term nursing care and osteoporotic fracture is very high. Moreover, the stress caused by fractures is way more critical. Therefore, the spot light must be put more on prevention of osteoporosis, Ca and vitamin D deficiency and falls amongst elderly. Identification of the elderly needs medical attention and care to reduce the mortality due to bone related morbidity is highly needed. Early detection may help in better result and reduce the total cost of the medical care. A wide screening in both urban and

rural India is the best way to strain out the population who are at risk. A clear picture of the bone health status of elderly is needed to be taken as a platform to plan national health strategies and action; and for healthy and graceful aging.

Interdisciplinary relevance

Prevalence of osteoporosis and osteopenia will give the relevant information to the Public Health Professionals and Policy Makers to formulate relevant health promotion strategies for elderly person. Effectiveness of high and low dose of Ca and vitamin D will make the supplementation very precise. It will help the Pharmaceuticals to formulate specific doses for prevention and treatment. Evaluation of present dietary calcium and vitamin D intake and its correlation with bone health status will provide evidence to judge the adequacy of the current RDA. Data on relation among exercise, life style and bone health will serve as an indicator to modify life style and health care practices of elderly to prevent and treat poor bone health. Data on correlation among hemoglobin and BMD may give an indication whether they should be considered as risk factors for poor BMD.

Significance of the study

- ✓ Current trend of bone health among the geriatric population of Vadodara.
- ✓ Modification of the guidelines to administer the therapeutic doses of Ca and vitamin D_3 to prevent and treat osteopenia, osteoporosis and hypovitaminosis D.
- ✓ Dietary intake of calcium and frequency of vitamin D rich food consumption among the Indian elderly.
- ✓ Dietary practices and relevant knowledge of elderly population about bone health.
- ✓ Life style of the elderly population and bone health.

Linking the large elderly population of India, scanty data on the scenario of bone health of the elderly and the major gaps in the diagnosis, management and treatment of osteoporosis enlisted research objectives were framed:

1. To determine the bone mass density and prevalence of osteopenia and osteoporosis among the elderly population of urban Vadodara.
2. To assess the socioeconomic status, anthropometric measurements, nutritional status, life style and health profile of the geriatric population of urban Vadodara.
3. To integrate the baseline parameters with BMD of the study population.
4. To analyze the serum calcium, vitamin D and hemoglobin levels and their association with BMD.
5. To assess the dietary intake and physical activity of elderly subjects and their association with BMD.
6. To supplement and investigate the efficacy of two different doses of Calcium and vitamin D_3 (high and low doses) and mega dose of vitamin D_3 on BMD, serum calcium and vitamin D levels.
7. To assess the impact of supplementation alone and supplementation coupled with daily weight bearing exercise on bone health of a sub sample elderly population.

A detailed review of the relevant literature has given in the next chapter i.e. review of literature.