

**Osteoporosis in Andhra pradesh, India, determinants and their correlation with bone parameters of men and women with osteoporosis hip fractures case control study**

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45<sup>th</sup> International Course in Health Development  
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KIT (ROYAL TROPICAL INSTITUTE)  
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A thesis submitted in partial fulfilment of the requirement for the degree of  
Master of Public Health

by

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India

Declaration:

Where other people's work has been used (either from a printed source, internet or any other source) this has been carefully acknowledged and referenced in accordance with departmental requirements.

The thesis **Osteoporosis in Andhra Pradesh, India, determinants and their correlation with Bone parameters of men and women with osteoporosis hip fractures Case control Study**

is my own work.

Signature:.....

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## **LIST OF ABBREVIATIONS AND INDIAN GLOSSARY**

AP	: Andhra Pradesh
APSCHE	: Andhra Pradesh State Council of Higher Education
ASHA	: Accredited social health activist
BMI	: Body mass index
BMD	: Bone mineral density
CCMB	: Center for cellular molecular biology
CHC	: Community health center
CME	: Continuous medical education
DEXA	: Dual energy x-ray absorptiometry
FAO	: Food and agriculture organization
FRAX	: Fracture risk assessment tool
FTOP	: Fracture think osteoporosis program
HBM	: Health behavior model
HRT	: Hormone replacement therapy
ICRIST	: International crops research Institute for the semi Arid crops
ICUROS	: International costs and utilities related osteoporosis Fractures study
IMR	: Infant mortality rate
IOF	: International osteoporosis foundation
ICMR	: Indian council of medical research
MMR	: Maternal mortality ratio
MHFW	: Ministry of health and family welfare
NOF	: National osteoporosis foundation
NIN	: National institute of nutrition
NRHM	: National rural health mission
NIH	: National institute of health
NFHS	: National family health survey
NHA	: National health accounts
PHC	: Primary health center
PQUS	: Peripheral quantitative ultrasound
SER	: Selective estrogen receptors
SHG	: Self help groups
TFR	: Total fertility rate
VDR	: Vitamin D receptor gene
WHO	: World health organization

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Finally, the beautiful and lovely touching part of my acknowledgements goes to my sons Piyush Raj, Sandeep, and my wife Amita who has been my constant source of inspiration. Finally, my thanks go to my aged father Sri.Sanjeeva Rao and sister Dr.Stella Dhinakaran, for their constant prayers.



## **ABSTRACT**

Osteoporosis cases are increasing all over the world and because of its fracture morbidity and mortality in the elderly and especially postmenopausal women and become a global health problem. In the developing countries, fracture cases are increasing as the longevity increases in these countries. Projections show Asia is going to have the highest incidence of cases because of its growing elderly population.

Indian Census shows there are about 163 million people above 50 years. The various scientific reports suggest 20% of women and 15% men are suffering from osteoporosis in India. In India, very limited studies are available on epidemiology of osteoporosis and fragility fractures.

The present study confirms the high prevalence of osteoporosis in both men and women equally in fractured case and the normal control population of the low socio economic sections. The study also shows fractures are occurring at the low body mass index (BMI). Study confirms low BMI is strongly associated with osteoporosis either as a risk factor or marker. The study also confirms that fractures are happening 10 years earlier than the western populations.

At present, there is no action plan for the management and prevention of osteoporosis in India. Therefore the study recommends a comprehensive population prevention strategy like community screening with low cost FRAX (Fracture risk assessment tool) tools for high risk groups. The study also highlights the urgent need of data base on the fractures.

The study concludes that there is urgent need for prevention strategies and guidelines to combat the silent epidemic of osteoporosis in the AP state and India.

**Word count:** 13 400

## **INTRODUCTION**

As a clinician I am working with National Institute of Nutrition (NIN), Hyderabad, India since the last 15 years. As a clinician, I was involved in the field-based studies of filariasis, malaria and the Leptospirosis. From the last five years, I was involved in clinical nutrition and bone health studies. Recently we have completed the study on Study of bone parameters of men and women with Osteoporotic hip fractures.

National Institute of Nutrition is one of the India's premier institute working under the aegis of Indian Council of medical research (ICMR), India. Sir Mc Carrison established NIN in the year of 1918 and it was recognized all over the world due to its pioneering works on Protein energy malnutrition (PEM). The institute is involved in nutritional research and solutions to the country nutritional health problems since last 80 years. The institute integrated with clinical, laboratory and the field based studies. The institute is working with a vision to achieve adequate nutrition to marginalized people, children and to the adolescent population by 2020.

Since Last ten years Clinical division of NIN is working on the bone health. The Main aim of the studies is to assess the osteoporosis risk factors and its prevalence in India. The studies involve biochemical, clinical and it is community oriented. The institutes want to generate Indian standards on bone parameters and particular to osteoporosis. As a part of the team, I was also involved in the field based and hospital based studies on osteoporosis. In India the silent epidemic of osteoporosis is emerging with increased incidence of fragility fractures. There is not much research on epidemiology and prevalence of osteoporosis fractures in India and in particular state of Andhra Pradesh. Research on osteoporosis is requires management and prevention of this global public health problem. This thesis on osteoporosis will through a light on the solutions for prevention of osteoporosis. In addition, developing a thesis proposal on osteoporosis is a good experience for me in upgrading my knowledge on this topic and solution to the people of AP, India.

## **CHAPTER 1. BACKGROUND INFORMATION ABOUT ANDHRA PRADESH, INDIA**

### **1.1. General information about Andhra Pradesh, India**

India is one of the ancient civilizations of the world and India is the seventh largest country, tenth industrialized nation, and sixth nation to have gone to space, and self-sufficiency in agricultural production (Know India, 2008). It extends from the snow covered great Himalayas in the North and the Tropical rain forests to the south. India has a population of 1,028 million (Census, India 2001), with 28 states and 7 union territories and recognized 22 national languages with 844 different dialects. The life expectancy in India is 63.9 for males and 66.9 for females. The sex ratio is 933 females for 1000 men, Crude Birth rate 24.8, Crude death rate is 8.9 and literacy is rate is 64.84% (census India, 2001). The Poverty in Rural areas is 28% and urban 26%, Infant mortality rate is 57 (1000 live Births), Maternal Mortality 450 (100000 live births), under nutrition among under five children is 46%, and only 33% population have access to sanitation facilities (Country health profile, WHO India 2005). According to the FAO, estimates 230 million constituting 21% of the total populations are undernourished (nutrition country profile, FAO, 2008). In India a social safety net and food safety, net available through the national Rural Health Mission (National Rural Health Mission, India 2005).

### **1.2. Demography situation**

The state of Andhra Pradesh (AP) is the fourth largest state by area and fifth by the population in India and its capital city is Hyderabad (AP online). Total population is 76.21 Million (census India, 2001) and the density of the population is 277 per square kilometer and among them 23% people are scheduled castes and Scheduled Tribes population (Census 2001). Among the total population 27.3 populations are living in urban areas. The total literacy rate is 60.5% among the male 70.3% among the female 50.4%. The sex ratio 978 (Female for 1000 males), the Total fertility rate is 1.9, Maternal Mortality ratio is 154 and people living below poverty line are 15.77% (AP fact file, WHO India). The health indicators are the Birth rate per 1000 is 19.1, death rate per 1000 is 7.3, and infant mortality per 1000 live births is 57 (AP fact file, WHO India).

### **1.3. Agriculture situation**

Andhra Pradesh is an agricultural state with an excellent agro-climatic condition. AP is the main rice producer in India and it is the rice bowl of India. Net irrigated area is 10.8 million hectares and (AP fact file). The staple

food is rice and cereals. People are getting energy from cereal-based diets 72% in rural and 62.5% in urban areas (AP Agriculture). Among the total agricultural labor women constitutes 55% to 65% of the total work force (Venketaswaran, 1991). Children are about 53.5% are the major work forces in small scale Beedi (Local cigarette) making Hybrid and cottonseed production units and among them 72% are girl children (Venketaswrlu, 2004). AP is also pioneering in agriculture education with one Agricultural University and Veterinary University with seven agricultural colleges and also strong Research and Development infrastructure and excellent institutions like CCMB, ICRISAT.

#### **1.4. Educational situation**

AP is pioneering in the education sector and offering education through a well-organized system throughout the state. To improve the literacy rate among the masses the government started so many projects in private and public partnerships. Education in the state is free for all up to 10<sup>th</sup> standard and for girls education is free up to graduation. Government is providing concessions to the lower classes to improve their educational standards. "SarvaShikhnaAbihiyan" is the government flagship program for universalization of elementary education to all the children and makes the education free and compulsory to 6-14 years and education as a fundamental right for this age group (School education, Government of, AP). In all the state run schools, government is providing cooked meal to all the children under the food program. Non-governmental organizations (NGOs) also involved in providing midday meal to schoolchildren. AP had 33 universities, 7 Deemed universities and 3 Central Universities (APSCHE, 2009). Education is nurturing in the state through Private and Public sectors. There are 79,449 Primary Schools, 3712 Junior colleges and 1300 degree and Postgraduate colleges (APSCHE, 2009) with renowned research institutes and universities.

#### **1.5. Economic situation**

Agriculture is the major source of income of the state and it is the second in mineral wealth in India. Hyderabad is the capital of AP is one of the main centers for Software industry in World has renowned Pharmaceutical industry and is responsible for bulk and generic drugs (AP online). AP has rich source of minerals like coal, oil & natural gas, bauxite, and limestone. AP has income generating centers and amenities like industrial development areas, industrial estates, growth centers and special complexes for chemicals, plastic, leather and software Technology Park. Railways, ports, road transport and shipping are very well developed. Due to the increase of industries and growing economy, more urban slums are coming up. There is lot of migration from the villages and other states for livelihood and living in the urban slums.

## **1.6. Women empowerment**

Women empowerment started in state with the anti liquor movement in 1990 and literacy movement started in 2000 with the help of the World Bank sponsored scheme (Women empowerment, World Bank, 2009). There are Self Help groups in all the districts involved in the preventing child marriages, child labor, women and child trafficking and the gender violence. In AP, around 1.2 million self-help groups (SHG) women purchased, the health insurance policies (World Bank, 2009). Still women and children are working in the unorganized sectors and the hazardous areas for lower labor wages. The Government had a strong health policy on women for equal access to health care and occupational health safety (NRHM, 2005).

## **1.7. Health system**

The state health system is working under the framework of The National Rural Health Mission (NRHM, 2005) scheme launched by Government of India. Main mission is to provide accessible health care to rural masses and deprived classes at the same time promoting decentralization. There is a monitoring and evaluation system with community participation (Commissionerate of Family Welfare, AP). The health system in the state is working towards ensuring equality and access to basic health care to all and specialized care at affordable prices, and use of resources with a long term sustainability. Government has strategy like universal access, increase community participation, setting up Self-supporting health insurance schemes. The government have specific action plans to tackle tuberculosis, blindness, leprosy, filariasis and HIV prevention and control programs. Along with Allopathic medical stream there are alternate medical systems like Unani, ayurvedic, Siddha and Homeopathic health care systems also providing health services (Commissionerate of Family Welfare, AP).

The government is committed to provide basic essential health services with special attention to Tribal people. The focus areas are on Adolescent health, Identification & treatment of high-risk pregnancies, institutional deliveries, neonatal care, full immunization, family welfare services, tribal health and rural emergency health transportation System (Commissionerate of Family Welfare, AP). The target is to reduce the IMR from the current level of 56 per 1000 live births to 30, to reduce MMR from 195 per 100000 live births to 100, to reduce TFR from 1.8 per women to 1.5, to increase Institutional deliveries from 69% to 95% by 2012 (Commissionerate of Family Welfare, AP).

## **1.8. Infrastructure**

### **1.8.1. Primary Health care**

In the state, the primary health care facilities are available for every 5000 in plain areas and 3000 populations in tribal areas. There are 1386 Primary Health centers, 34 Filariasis clinics in endemic areas, 104 Leprosy control units, 24 District Tuberculosis control units and 45 medical mobile units to outreach populations. Seventy percent of the health care is catering through the private health care facilities (Health status, MHFW, Government of AP).

### **1.8.2. Secondary Health care**

Andhra Pradesh is first in the country, which have first referral Hospital services in the country. In the secondary health care, there are 228 hospitals with a capacity of 16,314 beds and with 11,131 staff. In private health care services rendered through small nursing homes with diagnostic facilities like X-ray, blood tests and ultrasound (Health status, MHFW, Government of AP).

### **1.8.3. Tertiary Health care**

In government, there are 10 medical colleges, teaching hospitals 32, Nursing colleges 03, and dental colleges 1, 3 Regional cancer Hospitals with total bed Capacity 14,035. In private health care corporate hospitals, nursing homes are catering the health care. AP has separate Health University for quality medical education.

## **CHAPTER 2. PROBLEM STATEMENT, OBJECTIVES AND METHODOLOGY**

### **2.1. Problem Statement**

Osteoporosis is a global health problem and socio economic burden in developed and developing countries to affluent and non-affluent societies (Cummings, 2002). Same report claims it is high in geriatric populations as with increase in age there will be reduction in the Bone mass and this leads to more risk of Osteoporosis and related fractures. Osteoporosis is a public health problem due to its devastating outcomes (Melton, 2001), and high incidence of fractures. Fifty percent women and 20% of men have a risk for fragility fracture in their remaining lifetime (Department of health, 2004). Osteoporosis causes more morbidity, disability, reduces the quality of life and fractures are major Public health concern all over the world. In European Union, every day 1700 fractures are occurring, and 650000 a year (Murray CJL, 1996). All over the world around 8, 00,000 elderly population are adding every month and world projections indicating by 2020 above 75 years of age population may increase up to 269million from 163 million of 2000 (Murray CJL, 1996).

Osteoporosis is one among the five Non-communicable diseases of aging. The treatment costs are more expensive after diabetes, hyperlipidemia, hypertension and heart diseases. The incidence is increasing in developing countries as the longevity increases in these countries (Genant, 1999). Osteoporosis not only causes fractures, it causes people to be bedridden with problems of back pain, loss of height, kyphosis, pneumonias and pulmonary thromboembolism. Prevention of the diseases and its associated fractures is essential for good health, quality of life, and independence among elderly (World Health report, 1997). Fragility fractures are most common at Vertebral (Spine), proximal femur (hip), distal forearm (wrist) and Proximal Humerus and the incidence of vertebral and hip fractures increase with age and wrist fractures level off after 60 years of age (Compston, 1993).

All over the world as the population increases women are out numbering the men in osteoporosis cases and it is becoming women's public health issue (Important disease facts, NOF 1999). Thirty percent to fifty percent of women and 15-30% of men have lifetime risk for, osteoporosis and osteoporosis related fractures all over the world (Randell, 1995). During the post menopause, period in the women and aging in men bones become weak and impairment of neuromuscular functions may lead to Osteoporosis. Therefore, Cummings (2002) claims osteoporosis as an increasing clinical and public health problem all over the world. World Bank estimates the number at 470 million people in 1990 and it may increase up to 1.2 billion by 2030. Among them, 76% belongs to the developing countries. It also

projected that India may be the second highest in the world after China in terms of postmenopausal osteoporosis cases (World bank, 1993).

Worldwide projections- total hip fractures in those above age 50 years will double from 1.5 million in 1990 to about 3 million in 2025 (Cooper, 1992). Asia is predicted to bear an increasing burden accounting for 26% of hip fractures in 1990 and probably 37% by 2025. The world's Osteoporosis "Time Bomb" is ticking, with projected global burden of Osteoporosis hip fractures expected to exceed six million by 2050 (Cooper, 1992). There is no much published data on socio economic status as a risk factor for Osteoporosis but smoking, malnutrition, Calcium deficient diet, more alcohol consumption, high physical activity without balanced diet are correlating with more fractures occurring in the low socio economic status people (Borg, 2001). A recent study (Satruguna V, 2008) from India showed that there is a strong correlation with poor bone health in low socio economic status. A study from North India shows Indian low socioeconomic children had lower bone mineral densities and high prevalence of clinical and Vitamin D (Raman, 2005) deficiency in normal healthy school going children.

Recent Observational studies showed that there is a huge gap between occurrence of Osteoporosis fracture and proper diagnosis and management (Giangregorio, 2006). In-depth interviews show that many patients with fragility fracture are not associating fracture with bone fragility and indicate that the fractures are associated with external factors like fall, or slipping on ice, accident or as their first break (Reventlow, 2006). Adherence to the osteoporosis treatment is very poor because of lack of knowledge and understanding (Cline, 2005). In most of the developing countries, there is a lack of screening programs and diagnostic facilities for Osteoporosis (Tucci, 2006).

Burden of Non-communicable diseases are increasing in all the developing countries and India is experiencing an epidemiological transition mainly reflecting on the growing burden of Non-communicable diseases due to life style changes (Aquigley, 2006). The WHO (WHO, 2005) projections show because of non-communicable diseases India may lose 237 billions \$ and have great impact on economic productivity in the coming ten years. Osteoporosis is widely prevalent in India and Osteoporosis fractures are responsible for morbidity and mortality in adult Indian women and men (Gupta, 1996). Scientific groups estimate that in India around 26 million people are suffering from Osteoporosis. Projected that it may rise up to 36 million by 2013 (Osteoporosis society of India, 2003). In most Western countries, the peak incidence of osteoporosis fractures occurs at age of 70-80 years but in India, it occurs 10-20 years earlier occurring at the age of 50-60 years (Alkel, 1999, Damodhran, 2000).



Population based interventions on health promotion; macro economic policies at primary level are required to prevent and to manage of non-communicable diseases (Greenberg, 2005). Due to the unexplored silent growing epidemic proportions of osteoporosis in the country, the study on epidemiology, determinants and analysis of case control study of India will provide inputs about the osteoporosis and its prevention. These inputs used for prevention of osteoporosis in the state of AP with available health resources with a local community setting. Due to lack of authentic epidemiological (Malhotra, 2008) data on prevalence, diseases pattern and its determinants in India and other developing countries the studies are needed to explore the effective prevention strategies for prevention and management of osteoporosis. Recent study (Joshi, 2006) show mortality due to Non-communicable diseases is increasing in the rural areas of Andhra Pradesh. In India, there are well-defined health policies and strategies for prevention of non-communicable diseases like cancer, metabolic syndrome and cardio vascular diseases. There is an urgent need to include and formulate policies and strategies for prevention and management of osteoporosis.

In the state of AP, private health care rendering 72% of services and the remaining by the public. In the public system, government is providing services through primary secondary and tertiary levels. The Primary health center (PHC) micro unit for the health services and it is catering to the poor and marginalized sections of the rural areas. At the primary health center level, there are no formal services for osteoporosis available. However, at Community health services (CHC) some primary services like X-ray and first aid treatment for osteoporosis available. At tertiary level all osteoporosis related prevention, diagnosis, treatment and rehabilitation services are available. The most sophisticated and accurate screening methods like Dual-energy X- ray absorptiometry (DEXA) are available in research and corporate hospitals in cities of AP.

Although the national health policy talks about non-communicable diseases in basic essential health package of services, osteoporosis is not included. There is no national policy on osteoporosis and treatment guidelines. The government of AP has implementing the Social safety net as part of National rural health mission (NRHM) at the PHC level to cater services to the poor. The scheme covers only the institutional deliveries and providing theater facilities for labor and communicable diseases and there is no provision for the non-communicable diseases.

Health care professionals are unequally distributed among urban and rural areas. Most of the population living in the rural areas has a limited

accessibility for the quality care. Because of expensive private health care people from the low socioeconomic group are seeking services from locally available traditional healer like bonesetters.

## **2.2. General Objective**

To explore the Epidemiology, the Determinants of Osteoporosis in, India and other countries, and analyze the case control study of Bone parameters of men and women with Osteoporosis Hip fractures in the state of Andhra Pradesh and to give recommendations on the prevention and control of osteoporosis.

## **2.3. Objectives**

1. Identify & Describe the Epidemiology of Osteoporosis and its trends in India.
2. Identify & Describe the Determinants that are responsible for Osteoporosis.
3. Describe the consequences of Osteoporosis.
4. Review the evidence based interventions to prevent the Osteoporosis
5. Provide recommendations on prevention and control of osteoporosis.

## **2.4. Methodology**

### **2.4.1. Study design**

This thesis is a combination of Descriptive Study based on literature review and Hospital based Case Control study on Bone parameters of Osteoporotic Hip fracture in the state of Andhra Pradesh, India.

### **2.4.2. Study methods**

#### **2.4.2.1. Search Strategy**

Most of the data obtained from Internet, KIT and VU libraries. The study material, references were collected from Pub med, WHO Web site , WHO India Web site , International Osteoporosis Society , Cochrane Library ,Indian Council of Medical Research Journal Consortium , National Institute of Nutrition library and annual reports , India. Some analyses and the conclusions in the thesis based on interaction with several researchers in the field.

#### **2.4.2.2. Case control study**

The primary data obtained through the case control on "Study of Bone parameters of men and women with Osteoporosis Hip fractures" from the National Institute of Nutrition, Government of India, and Hyderabad. This study conducted in the city of Hyderabad, India between 2005-2008. The study methodologies is further described in chapter 4.

#### **2.4.2.3 Key words**

Osteoporosis, Osteopenia Bone mineral density, Fractures ,Peak bone mass, risk factors, prevention Strategies, Determinants, Hip fractures, Forearm fractures, Vertebral fracture, Diseases burden, Secular trends, Geographical variation.

#### **2.4.2.4. Inclusion criteria**

References and Literatures Were quoted from index journals with good impact factor. Only literature written in English that published in the internet.

## CHAPTER 3. EPIDEMIOLOGY, DETERMINANTS AND CONSEQUENCES OF OSTEOPOROSIS IN INDIA

### 3.1. Definition of Osteoporosis

“Osteoporosis is a systemic skeletal disease characterized by low bone density and micro architectural deterioration of bone tissue with a consequent increase in bone fragility” (Consensus Development conference, 1991).

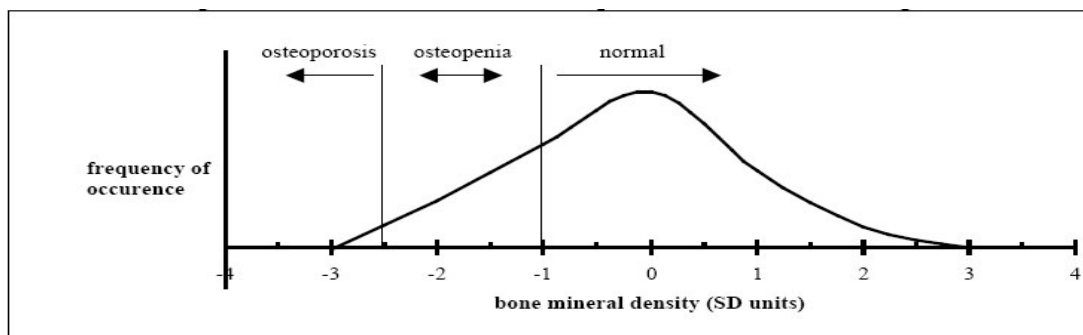
The WHO guidelines (WHO, 1998) on fragility fractures of osteoporosis states “a fracture caused by injury that would be insufficient to fracture a normal bone the result of reduced compressive and or torsion strength of bone”

The clinical fragility fracture Brown (2002) states that as a “fracture occurs as a result of minimal trauma, such as a fall from a standing height or less or no identifiable trauma”.

Genant (1999) defined “osteoporosis as a skeletal disorder characterized by compromised bone strength predisposing to an increased risk of fracture; it is a major public health problem throughout the world”.

Measurement of Bone Mineral density (BMD) is Gold Standard for diagnosing of Osteoporosis and it is the central component of any provision that arises from the International agreed definition of Osteoporosis (John A Kanis, 2002).

**Fig 1. WHO Classification of Osteoporosis**



Source: (WHO, Technical report, 1994)

"*Normal* : a value of bone mineral Density not more than 1SD below the young mean value ( $T > -1$ )  
*Osteopenia* : a BMD value lies between 1 and 2.5 SD below the young adult mean value ( $< -1.0$  and  $> -2.5$ )  
*Osteoporosis* : a BMD value more than 2.5 SD below the young adult mean value ( $T < -2.5$ ).  
*Established Osteoporosis*: a BMD value more than 2.5 SD below the young adult means value ( $T < -2.5$ ) in the presence of more fragility fractures."

### **3.2. Epidemiology of Osteoporosis**

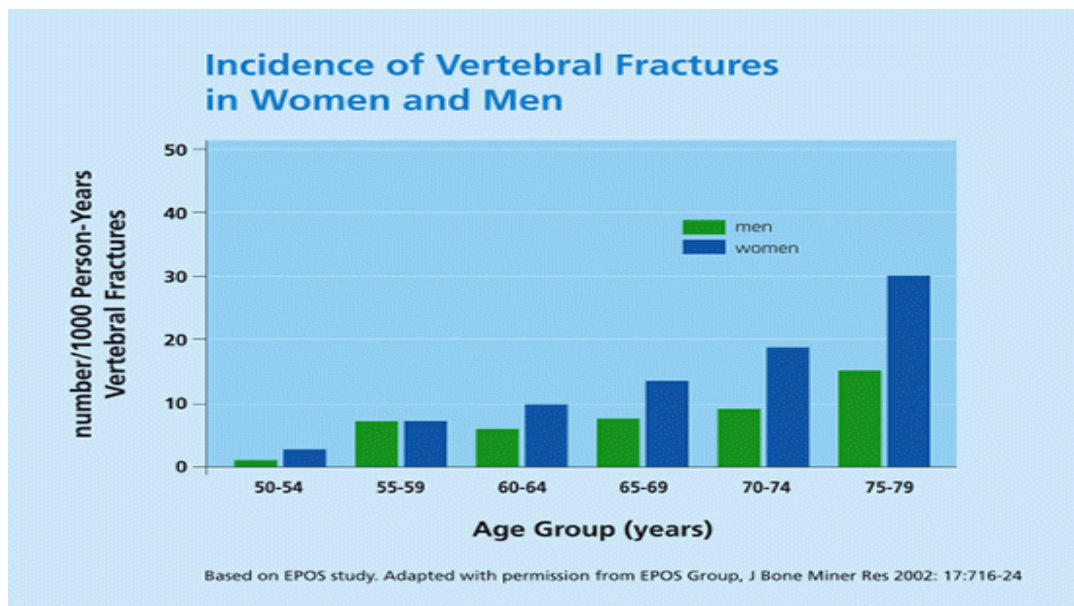
Osteoporosis identified as major public health problem because of its relationship with fragility fractures (Holoroyd, 2008). The incidence of Osteoporosis measured indirectly, as the incidence of fractures attributed to the condition, while prevalence measured by the frequency of reduced Bone mineral density or numbers of people with vertebral deformity (Woolf, 2003). Several studies estimated the global burden of Osteoporosis by the current and predicted number of hip fractures (Johnell, 2004). There is an inverse relation between bone density and fractures and the decreases of Bone mineral density (Marshall, 1996). A prospective population based study of Rotterdam, shows the decline of age adjusted Hazard Ratio per SD decrease in femoral neck Bone Mineral Density was 1.5 for women and 1.4 for men at the age of 50 (Schuit, 2004). Osteoporosis fractures occur mainly in the trabecular bone areas of the skeleton (Holoroyd, 2008).

A Meta analysis show previous fractures are the major risk factor for future Osteoporosis fracture and chances to get a another fracture are doubled (Bonaiuti,2002, Kanis, 2004). Cohort studies show those who had a vertebral fracture have a 1.8-3.8 fold excess of subsequent hip fractures are reported (Kotowicz, 1994, Lauritzen, 1993) There is a twelve-fold increase risk of fracture those who had two are more vertebrata fractures with low Bone mineral Density (Ross, 1993).

In India around 61 million people are affected and suffering with Osteoporosis (Joshi, 1998). Epidemiological data is not available on prevalence and incidence of osteoporosis. However, hospital data suggest that men are more prone to osteoporosis (Malhotra, 2008), out of 421 hip fractured iliac crest biopsies samples, 141 had osteoporosis (Vaishnava, 1974), 20 to 25% prevalence among 45 years aged in north India (Sharma, 2006). Population based studies from India show osteoporosis prevalent in 3% of males and 8% of females (ICMR annual report, 2007). However, other studies show, women of low socio economic 29% (Shatrugna, 2005), rural areas 28.2% male 44.1% in females (Abraham, 2009), and urban areas 48% at the lumbar spine, 16.7% at the femoral neck (Paul, 2008). Study

from south India show 50% of postmenopausal women are osteoporosis and Vitamin D deficient (Thomas, 2008).

**Figure 2: Incidence of vertebral fractures in women and men of EPOS study**



Source: Journal of Bone mineral Res 2002:17:716-24.

### 3.3. Consequences

Fractures of the Vertebra (spine), Proximal femur (hip), and distal forearm (wrist) osteoporosis became clinical and public health problem and these fractures are causing disability and are responsible for high medical bills in the world (Cummings, 2002).

#### 3.3.1. Fractures

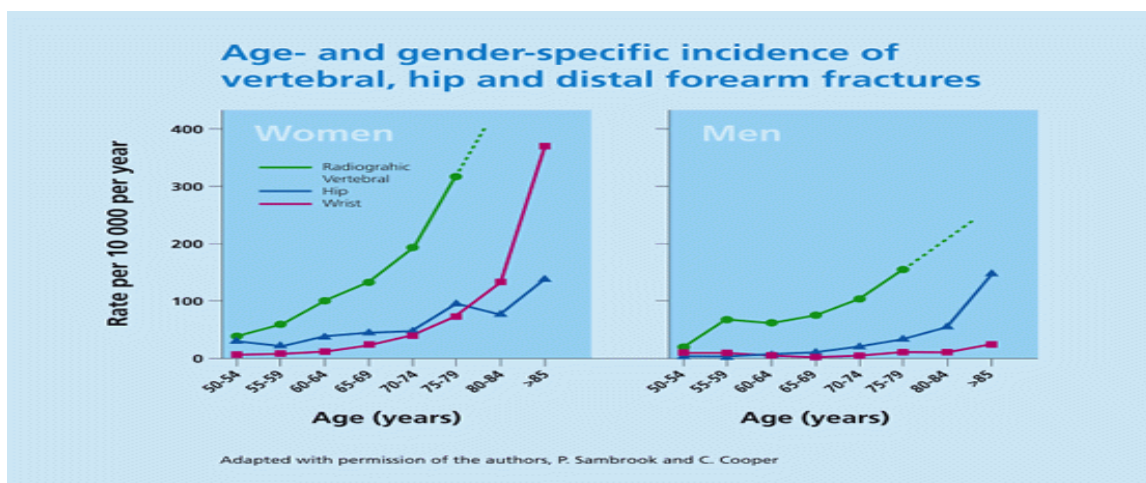
##### Hip fractures:

Hip fractures are causing more disability, mortality and hospital admission as an outcome of Osteoporosis (Melton, 2001). In the elderly population hip fractures are major public health problem and to reduce the incidence rate it has requires a time bound strategic health plans to combat this public health issue (Cooper, 1993). Hip fractures are the International barometer of osteoporosis and correlates with Low bone mineral density, more disability, more costs to repair (Cummings, 2002). Low bone mass is the main determinant for bone fragility and leads to the fracture and main risk factor for hip fractures (Nevitt, 1994). Osteoporosis hip fractures are happening

because of fall from standing height occurs spontaneously (Melton, 1995). As age increases, Hip fractures rates in men and women also increase all over the world (Melton, 2001).

In Africa and Asia, more osteoporosis hip fractures are happening in urban areas and there is no female preponderance (Adebajo, 1991). In the well developed cities of Asia and Latin incidence of osteoporosis hip fracture cases are increasing (Kanis,2002).In India Osteoporosis hip fractures are occurring in both sexes equally and fractures are happening at the age of 60-70 years (Sankaran,2000). In India, low socio economic sections have 29% prevalence and other study shows 20-25% prevalence in northern India (Shatruguna, 2005, Sharama, 2006). The mean hospital stays for hip fractures are 30 days and hospital bed days are equally comparable with breast cancer, cardiovascular diseases, and chronic obstructive pulmonary diseases (Kanis 1997).

**Figure 3: Age-and gender –specific incidence of vertebral, hip and distal forearm fractures:**



**Source:** Age-specific and sex-specific incidence of radiographic vertebral, hip and distal forearm fractures. (Sambrook et al. Lancet 2006; 367:2010-8)

### Vertebral fractures:

There is very limited epidemiological information is available about osteoporosis vertebral fractures. The impacts of vertebral fractures are low but these fractures cause loss of height, kyphosis, back pain, loss of mobility and leading to increased of further fractures (Gold, 1996). When compared with hip fractures age related increase is less there is no much variation in the incidence rates among different countries (Neil o', 1996). The EPOS

study as indicates that age increases the incidence of fractures also increase in both men and women (Fig -2 )(EPOS study, 2002). Osteoporosis vertebral fractures prevalence in Asians as similar in Caucasians (Ross, 1995). One fourth of these fractures are happening because of falls also happening in routine activities like bending or lifting of light objects, and heavy loads (Elaine, 2005). The epidemiological data of vertebral fracture shows Hispanic and African American women have lower fracture rates than whites and these fractures impact best measured, not based on their frequency, but effects on quality of people's life (Bauer, 1987, Aloia, 1996).

### **Forearm Fractures:**

Wrist fractures are most commonly occurring in the perimenopausal women and it is lower in men (Melton, 1995). These Osteoporosis fractures are common in middle aged and elderly due to simple fall on the out stretched hand and these fractures are leading cause for other osteoporosis fractures in the future (WHO Technical Report, 1994, Silman, 1995). Most of the wrist fractures are occurring at the women age of 65 and in the men at this age very low incidence of fractures are recorded (Fig 3) (Sambrook, 2006). Osteoporosis forearm fractures are termed as fragility fractures happening in the women who are losing their weight involuntarily (Ensurd, 1997). Scientific evidence shows these fractures happening due to low bone density, but these fractures not cause mortality (Seelay, 1991, Cooper 1993). These forearm fractures occurring more in the postmenopausal women because of more bone loss (Cummings, 2002).

### **Secondary complications:**

Osteoporosis fractures of vertebrae cause Spinal cord compression (Kochbati, 2009), and hip fracture causes a vascular necrosis. Hip fracture causes a permanent disability, malformations, and needs hospitalization, and surgical intervention (NOF, web site). They can also cause immobilization with complications of pneumonia, pulmonary thromboembolism, Back pain, loss of height and diminished quality of life.

### **3.3.2. Diseases Burden**

Osteoporosis fractures are inflicting a major economic losses on health care systems world wide and 1997 estimates showing the world spending around US\$ 131- 5 billion directly and indirectly on Osteoporosis (Johnell, 1997). The Worldwide Osteoporosis fractures showing that it is contributing 0.83% of the global burden of non-communicable disease and 1.75% global burden in Europe and Hip fractures accounted for 0.82 million Daly's in women, accounting for 41% of the global burden of Osteoporosis (Johnell, 2006). Osteoporosis fractures are amounting 1% of the Daly's among Non Communicable diseases in the World (WHO Scientific Group, 2004).



### **3.3.3. Health costs & access for individuals**

All over the world, the health care system is spending so much of money on diagnostics, treatment and prevention measures. The health costs mainly based on the costs of the osteoporosis fractures (Johenell, 1997). The United States health care system spends around 17 Billion \$ annually and projected costs by 2040 is around 50\$ billions (National Osteoporosis foundation, 2003). United Kingdom annually spending 1.7 billion \$ for osteoporosis prevention and management (Holroyd, 2008). The cost of the hip treatment are Italy \$8346, France \$9907 (Bouee, 2006), Singapore \$7367 (Wong, 2002) and third world country Turkey \$5983 (Mine Durusu, 2009). Japan spending 73.1million yen annually for treatment and management of osteoporosis fractures (Hayashi, 2009). The osteoporosis related direct costs are more than the annual costs of stroke, breast cancer, diabetes, or chronic lung diseases (Miller, 1999). Worldwide health expenditure on osteoporosis is rising more than the general inflation rate in all the countries (Cummings, 2002).

Recently International osteoporosis foundation (IOF) started an International Costs and Utilities Related to Osteoporotic Fractures Study (ICUROS) to analyze the health costs about osteoporosis. At present, only the Swedish have health costs model. In India, there is no data available on health costs of osteoporosis. In India, government is spending 4.6% of its GDP on health. Total public health expenditure is 20.3%, private expenditure is 77.4% and the external support is 2.3% (NHA of India). India is spending 0.4% of total health budget on the non-communicable diseases (NHA of India, 2001-2002).

### **3.4. Determinants responsible for Osteoporosis fractures**

#### **3.4.1 Peak bone mass development**

For the prevention of Osteoporosis development and maintaining the peak bone mass is most vital for the bone health. Peak bone mass is the bone tissue and the outcome of the skeletal maturation (Bonjour, 1996). The consequences of Osteoporosis appear at the later life but it develops from child hood and adolescence period. The peak bone mass is the major determinant for osteoporosis, and 40% of bone mass develops between from the late childhood and the early adolescence (Cummings, 1999). The calcium and vitamin D, physical activity at the childhood and adolescent age has positive effect on the attainment of peak bone mass (Patiff, 1982). A recent study from India shows that peak bone mineral density is attained in healthy males at the age of 25 years and in females at 28 years, (UN published ICMR multi centric project). This is significantly **less** than in the western counterparts.

### **3.4.2. Genetic factors**

Genetic factors have a role on Bone mineral Density at the age of 20-30 and bone mineral loss at post menopause period (Brown, 2005). Fifty percent of the Peak bone mass, bone geometry, bone strength, bone architecture depends on genetic predisposition (Cooper, 1999). Some studies show that if a mother has Osteoporosis children have a risk for Osteoporosis fractures (A systemic Review of Swedish Council). Other studies indicate that seventy-five percent peak bone mass depends on the genetic factors like Vitamin D receptor gene, Estrogen receptor gene, Collagen receptor gene (Cooper, 1996, Uitterlinden, 1996). The Scientific reports show that black women had High Bone mineral Density, and fewer incidences of hip fractures than the other populations (NIH, 2000). Women who had a history of a maternal hip fracture are two times more at risk than women without similar family history (Albrand, 2003). Indian Studies showing vitamin D Receptor (VDR) gene polymorphism, Estrogen receptor Alpha polymorphism gene associated with decreased bone density in Indian postmenopausal women Mitra, 2006).

### **3.4.3. Gender and Sex**

All over the World life time risk of 30 to 50% of women and 15 to 30% men are suffering with Osteoporosis (Randell, 1995). Globally incidence of Osteoporotic fractures in women is more than the total incidence rates of heart attack, Stroke and Breast cancer in women (Riggs, 1995). In the lifetime, Women are three times more at risk for osteoporosis than men (Healthy people 2010 objectives, 1998). Osteoporoses become a women's public health problem because women are more in number in the geriatric population than the men (Important diseases facts, 1999).

### **3.4.4. Age**

As age increases, there is a risk for osteoporosis and increase incidence of fractures in both women and men equally (Melton, 2001). There is a decrease of bone density when the age increases. India old age populations are increasing rapidly because increase of longevity and improving living standards. The population pyramid show there is increase above fifty years population among both men and women.

### **3.4.5. Menopause**

In woman, postmenopausal osteoporosis is the commonest and causing more morbidity and mortality (Shah Rashmi, 2005). A same report considers it is considered as a major public health problem in women and easily preventable. In the world, average age for women reaching menopause is around 52 years, but in India is comparatively less and more hysterectomy were reported in urban India (Amarjeet, 2008). According World Bank estimates India by 2030 the postmenopausal women population will be the

second highest in the world after China (World bank development report, 1993). Because of early menopause in women, leads to reduction in bone mass and prone for triple risk for early fractures.

**Surgical menopause:** In India Surgical, menopause is one of the risk factor for Osteoporosis. In India, some parts of the country hysterectomies are taking place at very early age and most of these people are more prone for Osteoporosis fractures. Surgical menopause leads to the decreased levels of estrogen and progesterone levels. This may lead decrease of Bone mineral density and risk for fractures at early age.

#### **3.4.6. Parity – lactation**

Studies from developing countries from Morocco, Vietnam, and Korea show parity and lactation have a detrimental effect on Bone mineral Density factor (Memon, 1998). Studies from South America shows nulliparous women had a more Osteopenia and Osteoporosis than the non-nulliparous women (Black DM, 1999). Prolonged lactation, period of amenorrhea and pre pregnancy weight have role on bone mineral density and studies show prolonged lactation leads to the loss of calcium and leads to the decrease of Bone mineral Density (Grimes JP, 2003).

#### **3.4.7. Medical factors**

Gastrointestinal disorders (Malabsorption, Inflammatory bowel Syndrome) Hematological disorders (eg: Thalassemia and Pernicious anemia) and Hypogonadal states, thyrotoxicosis, anorexia nervosa are the lead causes for secondary Osteoporosis in men and women (National Osteoporosis Foundation, 2003). Steroids usage is rising in routine treatment schedules in India .Studies showing increased usage of steroids may lead to reduced bone loss and lead to increased fracture risk (NIH,2001). The recent meta analysis from Cochrane show use of steroidal contraceptive like Depot medroxyprogesterone acetate (DMPA) will reduce the bone mineral density and prone for fractures (Lopez,2006).

#### **3.4.8. Nutrition factors**

**Vitamin D:** Vitamin D deficiency may precipitate Osteopenia, Osteoporosis and more risk for fractures and it plays very important role in bone homeostasis and bone health (Holick, 2007). Vitamin deficiency is common in the Middle East, India, China and Japan and less common in Northern Europe and South East Asia (Johnell, 2005). Studies showing low levels of Vitamin D in the elderly and causing for more Osteoporosis fractures especially Hip fractures and Vitamin deficiency will increase the PTH production and leads to the high bone turn over and bone loss (Clinical Guidelines, Royal College, 1999). In India Low vitamin D level are

responsible for lower bone densities and poor bone health (Malhotra, 2008). The study show there is high prevalence of Vitamin D deficiency in the schoolchildren of North India (Raman, 2005).Recent study show there is a widespread Vitamin D deficiency all over the world including India and responsible for osteoporosis fractures and going to be major public health problem (Mithal,2009).

**Protein :** Malnutrition is continues to be the major chronic health problem in Asian and African countries and less intake of protein diet delays the building of peak bone mass at childhood and adolescence and these people are at risk of Osteoporosis at later life (Rizzoli,1999). The scientific report show there is high incidence of hip fractures and low bone densities among malnutrition and the under nutrition people because of low protein intakes (Lipschiz, 1995). Western studies showing high intake of calcium and high protein diet is the responsible for high incidence of Osteoporosis prevalence in the western populations (Hegsted, 1986, Abelow, 1992). In Western population, more Calcium with high protein diet may lead to the negative calcium balance and leading to the decrease of bone mineral density and leads to the Osteoporosis.

**Calcium:** Cross sectional studies showing higher intake of calcium in the childhood and adolescent age it may increase the bone mineral density in children adolescent and the young women (Kanis, 1999, Meunier, 1999). Dietary Calcium deficiency and Low body mass index (BMI) play important role in on lean men and women lead to the reduction in Bone Mineral density (Nguyen, 2000). Study from India show in the low socioeconomic groups the Calcium intake is only 300 mg/dl, which is 700mg less than the required amount (Satruguna, 2008). India about 40% people from Low socio economic groups suffers with Chronic Energy Deficiency and have inadequate energy, protein Calcium and other micro Nutrients (NNMB,2002, Satruguna,2006). So many medications like Diuretics, anti Convulsions, Non Steroidal anti Inflammatory medications Corticosteroids, Immuno suppressive medications and some antibiotics will impair the Calcium absorption (Nancy, 2006).

**Vegetarianism:** Indian study showing vegetarians have 50% risk of osteoporosis and 98.82% are osteopenic (Ashwani, 2005). Vegetarian diet consists of less calcium, less absorption of calcium and poor bioavailability may be the reason for Low bone mineral density and risk for Osteoporosis fractures among the vegetarians (Barr, 1998).

### **3.4.9. Physical activity**

**Physical inactivity:** The cohort studies showing Physical inactivity in the old age populations are responsible for decline of bone mass and the major risk factor for Osteoporosis fractures (Coup, 1993, Espallargues, 2001). Cross sectional studies shows weight bearing exercises have beneficial impact on the bone mass, development of peak bone mass and reduces the bone loss and the mechanical stress (Bradney, 1998, Marcus, 1996). Studies from China shows more physical exercise by postmenopausal women have a substantially reduction in BMD loss and have positive health effect was observed (Qin L AU, 2002). Some studies physical activity have a strong association with nutrition and bone health and shows physical activity be beneficial only calcium intakes will be more than 1000 mg/day and there will be no effect if it is less than 1000mg/day (Murphy, 2003).

**High physical activity:** European vertebral osteoporosis study (EVOS) studies shows high physical activity leads to the fractures in men (Silman,1998 ) and other study show high physical activity is more associated with hip fracture than the other fractures (Gregg,1998). An Indian study shows Low Socio economic people have poor bone health instead of high physical activity because of inadequate nutrition (Satruguna, 2008).

### **3.4.10. Lower body weight and Body mass index**

Literature shows low Body mass index (BMI), a measure of body composition, may be associated more no of Osteoporosis fractures, and osteoporosis (Siris, 2001). Low body mass index associated with lower peak bone mass and have leads to more bone loss and leads to the osteoporosis and osteoporosis fractures (Burger, 1998). Epidemiological studies shows low body weight is the one of the main determinant and risk factor for hip fractures (Ensurd, 1997).In European studies shows if BMI less than 19kg/m<sup>2</sup> are at risk of Osteoporosis Hip fracture (Johnell,1995).

### **3.4.11. Low exposure to sun light**

The multi centric and cross sectional studies showing there is a strong association between less exposure to sun light leads to the hip fractures in the age groups of above 50 years(Johnell, 1995). Vitamin D is essential for bone health and had an influence on growth and development of children and its deficiency leads to the increased bone turn over, enhanced bone loss and fracture risk (Parafitt, 1998, Lips, 2001). In developing countries especially in India, vitamin D levels are comparatively lesser than Western

counterparts are and studies shows there is a correlation with Vitamin D levels and bone mineral density (Arya, 2004).

### **3.4.12. Smoking**

India is producing third worlds tobacco and NFHS2 data show smoking prevalence among above 30 years of men is 41.2% and 18.2% of women (Tobacco use, WHO, India). A case control study from USA show current smokers had a risk of hip fracture OD 2.27 (95%CI 1.22-4.21) and the former smoker had a risk of OR 3.72 (95% CI 1.59-8.70). Large cohort study on smokers and non smokers followed for 12 years show women who smokes more than 25 cigarettes or more had 1.6 times risk for hip fracture than the (95% CI ,1.1-2.3) non smokers (Cornuz,1999). Studies identified strong association between cigarette smoking and risk of Osteoporosis considered as Public health problem and showing deficit in spinal bone density of 1.5% and Hipbone density 1.1% in men and women 1.5 and 0.4% (Egger, 1996). prospective and cohort studies shows smoking will decrease the Bone mineral Density and leads to the risk of Osteoporosis fractures in both men and women and also studies demonstrating that quitting smoking may help to reduce the fractures (Forsen,1994). Studies showing smokers have lower retention capacity of calcium and lead to bone loss (Krall, 1991). Cigarette smoking in women reduces the Bone mineral Density and leads to early menopause, reduced body weight and lead to metabolic break down of exogenous estrogen in women and causes fractures in women (Seeman, 1996). Epidemiological studies showing cigarette smoking is the independent risk factor for hip fractures in men and women (Law, 1997).

### **3.4.13. Alcohol consumption**

Meta-analysis showing low and moderate alcohol consumption is not a risk factor for Osteoporotic fractures (Espallargues, 2001). Prospective studies shows high consumption of alcohol have an increased risk of hip fractures five times in men and women because of reduced stability, and poor nutritional status individuals (Hernandez, 1991, Hoidrup, 1999).

### **3.4.14. Environmental factors**

There are some toxins like lead , cadmium, aluminum have effect on skeleton and constant exposure to these toxins may people land up with Osteoporosis and prone for fractures (Alfven,2000, Staseen,1999). Indian children exposed to the Lead and other toxins from early childhood.

Exposure to toxins at childhood may play a role in onset of Osteoporosis at their adult life (Abhay , 2006).

### **3.4.15. Geographical Variation**

The incidences of Osteoporosis fractures widely differ from one geographical area to the other demonstrating substantial geographical variation (Kanis, 1991). People living far from equator had a higher incidence of fractures than those who are staying near the equator (Chang, 2004). The incidence of hip fractures are more in Caucasians, Scandinavian than the North America and even Europe hip fractures incidence rates are different from each country (Elifors, 1994, Johnell,1992). Lower life expectancy may be a reason for lower incidence rates in developing countries (Morales, 2004). Osteoporosis hip fractures incidence rates are more in urban than rural areas and urban population had lower bone mass (Gardsell, 1991). Fracture rates and prevalence of Osteoporosis are different in different ethnic groups living in the same region like in Singapore; hip fractures are more in the Indian population than the other ethnic groups (Melton, 1995). A study shows Lower Spinal Bone mineral density is comparatively less in Indo Asian women than the Caucasian women (Mehata, 2004). Study from Vietnam results showing in the pre menopausal women prevalence of osteoporosis was higher in urban areas than the rural areas (VU, 2005).Scientific reports describe osteoporosis is the outcome of the modernization and incidence of osteoporosis fractures are more in urban than the rural areas (Chatlert Pongchaiyakul,2005). In China and other developing countries, bone mineral densities are different between urban and rural population because of rapid transition towards urbanization (DuX, 2001). Because of rapid urbanization in Hong Kong and other parts of Asia lower incidence of hip fractures rates were reported in rural than the urban areas (Lau, 1996).

### **3.4.16. Secular trends**

Increase of life expectancy all over the world and increase of old age population, increase of financial and health costs of the osteoporosis may be doubled in the future (Cooper, 1996). There is negative impact on bone mass or risk of falling is influencing the rise of fractures in successive generations of the elderly (Mertyn CN, 1999). In developing countries in the process of developmental transition the countries like Hong Kong Osteoporosis fractures cases are rising but in western countries it reached plateau (Royal college, 1999, Kannus P, 1996). Studies show there is positive correlation with Birth weight, short birth length at the time of delivery correlated with Osteoporosis fractures at the adult age, and infant weight can predict the future fractures (Cesar, 2008). Increasing trend of

fracture cases in India and other countries because of Good screening procedures, Availability of good Diagnostic techniques and underestimates the future projections (Obrant KJ, 1989).

#### **3.4.17. Ethnicity**

The bone mineral density was varies between different ethnic groups and blacks had a more BMD than Caucasians and Asians had a less bone mineral density (Barrett, 2005). Fractures rates are lower in the blacks and Asians than the whites are and Hispanics had higher fracture rates (Morton, 2003). Osteoporosis hip fractures are more in Caucasians than the Black and Asians (Maggi, 1991).



## **CHAPTER 4. CASE CONTROL STUDY OF OSTEOPOROTIC HIP FRACTURES**

### **4.1. Title of the project**

“Study of bone parameters of men and women with Osteoporotic hip fractures”

**Study period:** 2005 to 2008.

**Collaborating Institutes:** National Institute of Nutrition, Hyderabad, India & Department of Orthopedics, Osmania General Hospital, Hyderabad, India.

### **4.2. Background Information**

The fragility fractures due to osteoporosis are responsible for much morbidity and disability in the populations. Among all fractures, hip fractures causing more disability, morbidity and high health costs (Cummings, 2002). In India, there is very limited data available on osteoporosis hip fractures and its epidemiological patterns. The study planned to generate bone parameters for the osteoporosis-fractured patients to prepare a treatment schedules with the bone mineral densities and to formulate preventive strategies for the management of osteoporosis.

### **4.3. Objectives**

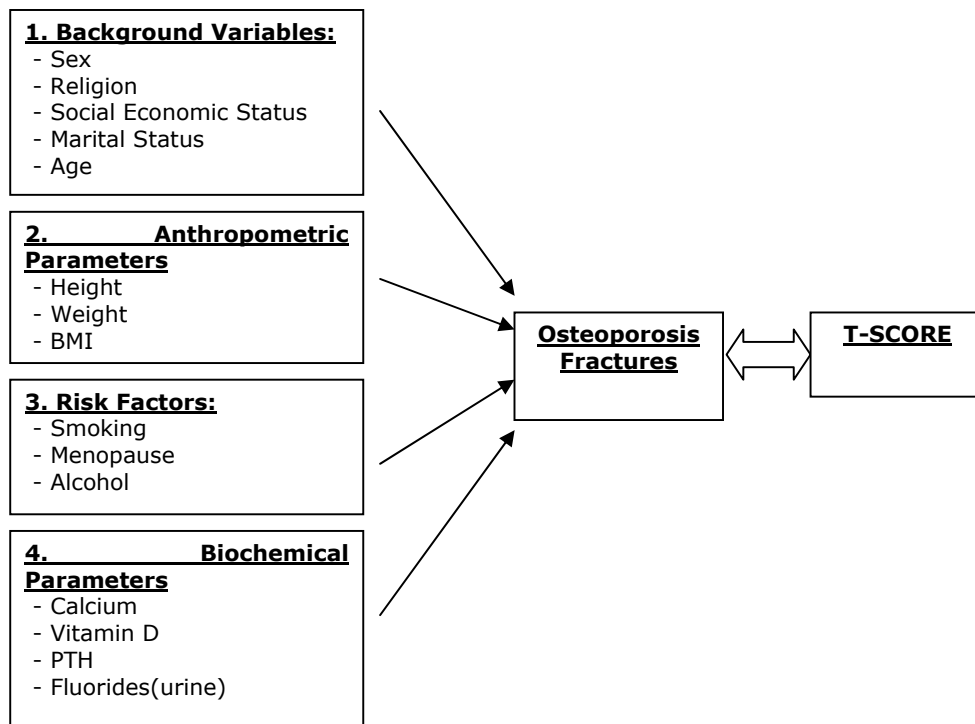
To study the bone parameters of men and women with Osteoporotic hip fractures to explore the associated factors contributing to fractures (see Figure 4).

### **4.4. Hypothesis**

It is hypothesized that Bone mineral density of patients with confirmed fresh Osteoporotic fractures is lower than the Bone mineral density of normal age and sex matched controls.

**4.5. Type of study:** Case control study

**Figure4: Flow chart of osteoporosis study parameters**



#### 4.6. Sample size

Assuming the 95% significance level, 80% of power, Standard Deviation of hip Bone mineral density 0.15 g/cm<sup>2</sup> and expected differences 0.07g/cm<sup>2</sup> and the required sample size can be calculated as both cases and control groups and for males and females.

$$n = \frac{(U+V)^2 (s_1^2 + s_2^2)}{(m_1 - m_2)^2}$$

$$n = \frac{(0.84+1.96)^2 (0.15^2 + 0.15^2)}{(0.07)^2}$$

$$n = 72$$

$$U=0.84, v=1.96, s_1=0.15, s_2=0.15, m_1 - m_2=0.07.$$

(Corlien M. Varkevisser, 2003)

## **4.7. Materials and methodology**

### **4.7.1. Methodology**

The Institute Scientific advisory committee, Institute Ethical Committee and the Hospital ethical committee approved the study proposal. The informed consent was obtained from the subjects.

### **4.7.2. Recruitment of subjects (Cases and controls)**

**Cases:** Adult men and women of 30-70 age groups who had a trivial injury admitted in the Orthopedics ward of the Osmania General hospital are recruited for the study. Osmania general hospital is the teaching hospital of Osmania medical college, Hyderabad, India. Osmania general hospital is rendering services to half million population of the surrounding areas, and *most of the patients are belongs to low socio economic groups*. The admitted fractured patients in the Osmania general hospital were transported to the National Institute of Nutrition (NIN), Hyderabad for DEXA, and other clinical, biochemical and anthropological studies. The National institute of nutrition, Hyderabad, is the premier research institute of India. The subjects recruited for the period of April 2005 to March 2008. A total number of 73 male and 73 female cases were recruited. Subjects enrolled who had fresh fractures of hip with in the last three months history of trivial injury and clinical evidence of osteoporosis. Background information about family history of fracture, personal history smoking, alcohol consumption, physical activity, physical activity, social status, parity, and menopause recorded.

**Controls:** Age and, sex, low socio economic background matched Controls selected from Low-income group Hyderabad, India. These subjects were recruited from the cross sectional study of "assessment of prevalence of osteoporosis in adult population in India" of Hyderabad. This study is a cross sectional study to estimate the prevalence of osteoporosis among adults of the urban population of India. The National Institute is the part of the multi centric study, which conducted prevalence studies in the city of Hyderabad. For this study a total number of 1500 subjects were recruited among the High socio economic group (HIG), Middle income group (MIG) and the low-income group (LIG). For each socio, economic group 250 males and 250 females were selected randomly with adequate sample size in Hyderabad center. For low socioeconomic group 250 males and 250 males selected. For osteoporosis fracture study age matched and sex matched a total number of 68 male and 46 female controls subjects of low-income group (LIG), Hyderabad were recruited. This was done as the cases also were recruited from the poorer segments of Hyderabad population. For the control subjects

DEXA scan, Anthropometry, biochemical investigation and clinical examination conducted at the National institute of Nutrition.

#### **4.7.3. Exclusion criteria for enrolling the subjects:**

**Chronic diseases:** Epilepsy, asthma, Cardio vascular accident (CVA), High blood pressure, diabetes, hyper and hypothyroidism, and malabsorption syndrome subjects excluded from the study.

**Drug Intake:** Those on medication of anti tuberculosis, on steroids excluded from the study.

**History of:** Delayed menarche, delayed puberty in males, polio or obvious physical disabilities, chronic immobilization problems, joint problems like rheumatoid arthritis, use of radioisotope for clinical investigation in the last month.

#### **4.7.4. Clinical examination**

Clinical examination was conducted and all vitals are recorded.

#### **4.7.5. Bio Chemical parameters**

Bio chemical investigations serum calcium (mg/dl), vitamin D (nanogram/nl), Parathyroid hormone (pg), and Urine Fluoride estimated with standard procedures.

#### **4.7.6. Anthropometric measurements**

The height was recorded with a stadiometer (seca Ltd), weight recorded from the DEXA, and the SECA balance recorded weight of the controls. The height and weight measurements were standardized.

#### **4.7.7. Bone Mineral density (BMD)**

The BMD of the subjects was recorded by the Dual -energy X -ray absorptiometry (DEXA). This is a non-invasive and less radiation exposure technique can assess the bone mineral content of the skeleton, and the specific sites (Genant HK, 1996). Dual energy X ray Absorptiometry is the Gold standard for diagnosis, confirmation of the risk for osteoporosis (Gonnelli S, 2005). DEXA is measurement on of Bone Mineral Density is the Gold standard method to diagnose Osteoporosis (Lochmuller EM, 2003). Bone mineral density of femoral neck, trochanter, wards triangle, inter

trochanter and total hip and spine was obtained by the Dual –energy X –ray absorptiometry ( DEXA, QDR 4500W; Waltham, MA, USA) and the scans were taken according to instrument manual. The quality control of machine checked daily with standard calibration.

#### 4.8. Statistical Methods

SPSS windows 14.0 windows version and EPI info are used for data analysis. For demographic profile and bone parameters and prevalence of osteoporosis by T scores the Chi square test and for the analysis of anthropometry and biochemical tests Data ANOVA test was used (George, 1989).

#### 4.9. Results

**Table 1: Overview of demographic data from the cases and controls.**

Variables	Cases n (%)	Controls n (%)	P value
<b>Sex</b>			
Males	74 (50%)	68 (60%)	
females	74 (50%)	46 (40%)	P= 0.12
<b>Religion</b>			
Hindus	95 (64%)	95 (84%)	
Muslims, Christians	53 (36%)	18 (16%)	* P<0.001
<b>Martial status</b>			
Married	143 ((97%)	113 (100%)	
Un married	5 (3%)	0	*P<0.05
<b>Communities</b>			
SC+ST	26 (18%)	41 (36%)	
BC	59 (40%)	63 (56%)	
Others	63 (42%)	9 (8%)	*P<0.001
<b>Age(Mean)</b>			
Males	59.1	56.1	P= 0.121
Females	63.6	60.9	P= 0.941

Statistical test used: Chi square test used.

SC (scheduled caste), ST (Scheduled tribes) (Lower caste population)

BC (Backward caste populations)

Others (Upper caste communities)

There is no difference in males and females between the cases and control subjects in the distribution. The cases and control are equally distributed between males and females.

The cases and controls were not matched with castes and religion. There is a significant ( $P < 0.001$ ) difference among the various social groups of cases and controls. The data show Hindus appear to have lower risk of osteoporosis fracture ( $OR = 0.34$ ). There is significant association ( $P < 0.05$ ) between married and unmarried subjects. The study show significantly more number of fractures is happening to the married people than the unmarried people.

The study show significantly ( $P < 0.001$ ) more fractures are happening to the upper caste population than the lower class population. In the control group, upper caste population consists only 8% of the total subjects. The selection bias may be one of the reasons for more number of fractures in upper caste population.

There is no difference between the mean age of the fractured cases and the healthy normal controls. The fractures are happening at the mean age of 59.1 for males and the 63.6 for the females. This confirms that fractures are occurring at the early age than the western populations.

**Table 2: Overview of Anthropometric parameters from the cases and controls**

Variable	Cases Mean (SD)	Controls Mean (SD)	P value*
<b>Height (cms)</b>			
males	164 (6.1)	160 (6.2)	* < 0.001
Females	152 (6)	147 (5.4)	* < 0.001
<b>Weight (kgs)</b>			
Males	48 (11)	49 (8.8)	P= 0.8
Females	45 (9.7)	47 (11)	P= 0.14
<b>BMI (Kg/m<sup>2</sup>)</b>			
Males	18 (3.7)	19 (3.3)	* < 0.27
Females	19 (3.9)	22 (4.3)	* < 0.002

The ANOVA test is used.

The mean height of the cases in male's females is 164 and 152 respectively. The cases mean height of both males and females ( $P < 0.001$ ,  $P < 0.001$ ) is significantly more than controls subjects. The controls height was measured

by Stadiometer (Seca) cases height was taken on a laying down position at the DEXA table. Normally we would expect osteoporotic people to be shorter, but measurement bias may have influenced the results. There is a weak significant association is between cases and controls weight in both males and females. The mean weight cases are 48 (SD 11) and 45 (SD 9.7). It needs to be noted that both cases and controls all have very low weights. The BMI is significantly ( $P < 0.002$ ) lower in the fracture cases of females than the controls. However, the BMI of the cases in female is lower than the normal BMI value. In the males, there is no difference between the cases and controls in the mean BMI. However, both cases and controls in males are lower than normal BMI. This may be the reason that there is no difference observed between the groups. The study confirms low BMI is strongly associated with osteoporosis either as a risk factor or as marker. However, the study shows that chronic energy deficiency (CED) was prevalent in the population and the cases.

**Table 3: Over view of risk factors of osteoporosis**

variable	Cases (total)	Controls (total)	OR	95%CI
Regular Alcohol consumers	17 (148)	19 (113)	0.64	0.3-1.37
Smoking any amount	33 (148)	22 (113)	1.19	0.62-2.3
Menopause	34 (74)	26 (46)	0.65	0.29-1.5

This study observed chronic smoking, regular alcohol and the post menopause had no significant impact on the occurrence of fractures. This may be due to the fact that controls may not be true representative. Normally, most studies show chronic smokers, chronic alcoholics and post menopausal period as the risk factors for osteoporosis.

**Table 4: Overview of Bio chemical parameters from the cases and controls**

variable	Cases Mean(SD)	Controls Mean(SD)	P value
Serum calcium (mg/dl)	8.7 (1.3)	9.2 (0.7)	< 0.20
Vitamin D (ng/ml)	14.4 (11)	33.8 (9.1)	* < 0.001
PTH (pg/ml)	56.7 (54.4)	37.6 (26.2)	< 0.081
Urinary fluoride ( $\mu$ g/g)	2.7 (5.5)	0.84 (0.4)	* < 0.001

Test used: ANOVA

Serum calcium normal range : 8.4 -10.2 mg/dl (AAS)

Vitamin D normal range --- : >15ng/ml (HPLC)

Parathormone normal range : 9-55 pg/ml (DSL)

Urinary fluoride normal range : < 0.80  $\mu$ g/g

There are lower levels of serum calcium and Vitamin D levels are observed in fractured cases. The vitamin D levels are significantly ( $P < 0.001$ ) lower in the fractures cases than the controls. There is high parathorormone activity in fractures cases than the controls but there is a weaker non-significant association between cases and controls. This study results also show high excretion of urinary fluorides in the fractured cases and significantly ( $< P 0.001$ ) more than the controls.



**Table 5: Prevalence of osteoporosis by "T" scores**

	"T" score	Cases	Controls	P value
<b>Hip</b>	<-2.5	26 (36%)	4 (6%)	
Males	-2.5- 1	35 (49%)	46 (68%)	
	>1	11 (15%)	18 (26%)	*P <0.001
Females	<-2.5	55 (74%)	24 (52%)	
	-2.5-1	18 (24%)	17 (37%)	
	>1	1 (1%)	5 (11%)	*P<0.001
<b>Wards Triangle</b>				
Males	<-2.5	41 (57%)	16 (24%)	
	-2.5-1	24 (33%)	44 (65%)	
	1	7 (10%)	8 (12%)	*P<0.01
Females	<-2.5	63 (85.1%)	28 (61%)	
	-2.5 to 1	11 (15%)	15 (33%)	
	>1	0 (0%)	3 (7%)	*P<0.001
<b>Spine</b>				
Males	<-2.5	44 (59%)	34 (50%)	
	-2.5-1	18 (24%)	25 (37%)	
	>1	12 (16%)	9 (13%)	P= 0.316
Females	<-2.5	63 (85%)	40 (87%)	
	-2.5-1	7 (9%)	4 (9%)	
	>1	4 (5%)	2 (4%)	P= 0.998
<b>Neck</b>				
Males	<-2.5	37 (51%)	13 (19%)	
	-2.5-1	27 (38%)	45 (66%)	
	>1	8 (11%)	10 (15%)	*P<0.001
Females	<-2.5	56 (76%)	19 (41%)	
	-2.5-1	17 (23%)	22 (48%)	
	>1	1 (1%)	5 (11%)	*P<0.001

Test used: Chi square test

The Bone mineral density "T" scores at hip region of the cases males 36% are osteoporosis and 49% are osteopenic. Bone mineral density of the cases is significantly lower than the controls (P< 0.001). In the female's fractured cases 74% are osteoporotic and 24% are osteopenic. The cases bone mineral density is significantly (P<0.001) lower than the controls at the hip region. However, in control population of males and females 6% and 52% had an osteoporosis.

At the Wards triangle, among the male cases, 57% are osteoporotic and 33% are osteopenic. Cases bone mineral density is significantly (P< 0.01)

lower than the controls. In the females 85.1% are osteoporotic and 15% are osteopenic. Cases bone mineral density is significantly lower than the (P<0.001) controls. At the Wards triangle, 24% males and 61% females had an osteoporosis in the controls.

At spine region 59% males among the cases had an osteoporosis and 24% are osteopenic and there is weak association with controls were noted. In the female cases, 85% had an osteoporosis, 9% are osteopenic, and weak association with controls was observed. However, in normal control subjects 50% males and 87% females had osteoporosis.

At the femoral neck 51%, male cases had osteoporosis and 38% are osteopenic. The cases bone mineral density is significantly lower (P< 0.001) than the controls. In the female cases, 76% had an osteoporosis, 23% are osteopenic. Cases bone mineral density is significantly (P<0.001), lower than the controls. However, in the controls 19% males and 41% females had osteoporosis.

#### **4.10. Study strengths and limitations**

The study of bone parameters and risk factors among fractured patients is a well-designed study and the first of this kind study in the country. This study gives inputs about mean age of the fracture occurrence and the range of the bone mineral density fractures in which fractures are happening. The study shows high prevalence of osteoporosis in both cases and controls. The study also confirms the lower levels of calcium and Vitamin D levels, high excretion of urinary fluorides and increased trend of parathormone. The study also confirms that fractures are happening 10 years earlier than the western populations. To know the population risk, controls may be recruited from the middle and high socio economic groups, with matched caste subjects, matched different religions subjects with required number.

## **CHAPTER 5. PREVENTION STRATEGIES**

Presently there is non-medical intervention available to reverse the effects of Osteoporosis and the only option is to reduce the incidence of Osteoporosis prevention by health education (Healthy people 2010 Objectives, 1998). Osteoporosis and its effects can be addressed through various prevention strategies. In this chapter, the available prevention strategies are outlined.

### **5.1. Primary prevention**

#### **5.1.1 Dietary Calcium supplementation**

##### **Childhood and adolescence**

Studies showing calcium supplements through food based and direct supplementation resulted in an increase in the bone density among the children (Bonjour, 1997). The same report stresses that calcium supplementation is more effective among the calcium deficient children. Studies show adequate consumption of milk at childhood and adolescence may prevent the onset of postmenopausal osteoporosis (Sandler, 1985). Calcium supplementation during childhood and adolescence has an impact on the risk of osteoporosis by influencing the peak bone mass (Llich, 2000). The calcium supplementation studies show that on children and adolescents there is an increase of bone mineral density (French, 2000). Study also claims that milk consumption at adolescent and childhood improves the peak bone mass and the bone mineral density particularly at the hip and spine (Teegarden, 1999).

##### **Adults**

Studies are showing that supplementations of calcium for young, perimenopausal, postmenopausal and pregnant women have an increase of bone mineral density (Dawson, 1990). The clinical trails on calcium supplementation shows the relative risk of vertebral fractures is 0.77 (95% CI 0.54-1.09), on non-vertebral fractures is 0.86 (95% CI is 0.43-1.72) (Craney, 2002), and hip fractures were less with RR 0.75 (95% CI is 0.60-0.94) (Kanis, 1992). Dairy products have better calcium absorption than the vegetables (Karkainen, 1997).

#### **5.1.2. Vitamin D supplementation**

A study from Finland shows 25% annual reduction of fractures among elderly people supplemented with 150000 IU of vitamin D annually (Heikinheimo, 1992). A study demonstrates that Vitamin D and calcium-combined supplementation leads to reduction in half of the non-vertebral

fractures (Dawson, 1997). Supplementations of calciferol (400-800 IU/day) among old subjects lead to an increase of bone mass density (Lips, 1996). Daily consumption of 400-800 IU of Vitamin D by the elderly is safe and it prevents the future fractures (WHO technical report series 921).

### **5.1.3. Protein supplementation**

Randomized clinical trails show that protein Supplementation among the hip fractured patients reduces the bone loss and hospital stays (Schurch, 1998). Protein supplementations to elderly population will increase the bone mass density and prevent the fractures.

### **5.1.4. Phytoestrogens**

Taking of phytoestrogens will have estrogens like effect and prevent the postmenopausal osteoporosis (WHO technical report series 921).

### **5.1.5. Health education**

Various studies show that heath education, information and training to people about non-pharmacological measures has changed the health behavior and their attitudes towards osteoporosis (Brecher, 2002).

### **Schoolchildren Education program on Osteoporosis**

Primary prevention should start from the late childhood and adolescent stage to prevent osteoporosis. By observing, the healthy dietary habits from childhood and adolescence will reduce the risk and burden of osteoporosis (Teegarden, 1999).

### **Campaign on Healthy diet**

The healthy and balanced diet with required calcium, protein, Vitamin C, and D, and minerals are required for good bone health (Heaney 2000).

### **5.1.6. Modification of behavior**

#### **Cessation of smoking**

Smoking impairs the metabolic system of the skeleton and is indirectly responsible for reduction of bone mineral density. Studies show that quitting of smoking will reduce the risk of fractures (Hoidrup, 2000). Meta analysis shows that there is lifetime risk by about 50% of osteoporosis fracture and more bone loss in postmenopausal period among the smoking women than the non-smokers (Law, 1997). Cigarette smoking had a lethal effect on the bone mass, and its starts from the young age (NIH, 2000).

### **Increase physical activity**

Structured, weight bearing and resistance exercises are useful to prevent fractures and to maintain healthy bone mass and muscle mass (Liu-Ambrose, 2004). A study on postmenopausal women shows physical exercises significantly improved the bone mineral density than the aerobic fitness program or a non-exercise control group (Kerr, 2002). Studies show that there is an increase of femoral neck bone density among those pre menarche girls who exercised (Morris, 1997).

### **Fall prevention**

Fall prevention is one of the primary preventions for osteoporotic fractures. American Geriatrics Society (2001) describes that modification of home environments with basic measures like removal of loose floor coverings, greasy surface areas, railings along stairways etc reduce falls. Similarly, they advocate that older people should be consistently counseled to modify the home environment in order to improve safety and reduce risk of falls. According to (Brixton, 2005) (Table 6) fall prevention is one of the main preventive measures to avoid the fractures in elderly.

#### **5.1.7. Awareness campaign among health professionals**

The scientific report shows that there is low-level of awareness among the health professionals about osteoporosis, its diagnosis, treatment and prevention measure in developing countries (Morales, 2000). There is an urgent need to conduct awareness campaign also among the health professionals and health care service providers about the diagnosis and clinical risk factors.

#### **5.1.8. Self-care management**

This is the best method for the high-risk group people. Activities like life style modification, regular weight bearing exercise, coordination, balance and flexibility, calcium and Vitamin D are the key elements for good bone health (Dalsky, 1998).

### **Chronic care model**

Chronic care model in public health is the most appropriate model for Osteoporosis prevention and treatment and self-management is the main component to reduce the health care costs as well as leading to less use of health care services (Bodenheimer, 2002). This model implemented in the high-risk groups promotes individual self-care to prevent future fractures.

## **5.2. Secondary prevention**

Secondary prevention starts with screening. There are three methods:

### **a). Screening**

There are many techniques available to screen osteoporosis like DEXA (dual –energy X-ray absorptiometry), peripheral quantitative ultrasound (QUS) and computer tomography. DEXA is a measurement of Bone Mineral Density and it is the Gold standard method to diagnose Osteoporosis (Lochmuller, 2003). Its sensitivity is less and specificity is very high. This is very expensive to use in the community screening. To predict and to estimate osteoporosis in the community, Qualitative ultrasound technique is very useful (Khaw, 2004).

### **b). WHO fracture risk assessment tool (FRAX)**

By using this tool, a ten-year fracture risk with the clinical risk factors can be predicted. This can be used with out the DEXA and it is very cost effective and useful for health professionals to prepare treatment schedules (Kanis, 2008).

### **c). Validated questionnaires**

There are many questionnaire available to identify the risk groups and for assessment of risk for high-risk groups (Cadarette, 2000; Richy, 2004; Cadarette, 2001). These are as follows:

- Osteoporosis self assessment tool (OST)
- The osteoporosis index of risk (OSIRIS)
- Simple calculated osteoporosis risk estimation (SCORE)
- Osteoporosis risk assessment instrument (ORAI)
- Age, body, size, No estrogens decision rules (ABONE).

The screened people will subsequently be treated with Pharmaceutical interventions:

#### **5.2.1. Bisphosphonates**

Many randomized trails demonstrated that treatment with bisphophanates has reduced the risk of spinal fractures, hip fractures and the peripheral fractures (Cranney, 2003).

#### **5.2.2. Hormone replacement therapy (HRT)**

HRT has been used primarily for the treatment of postmenopausal osteoporosis for long time. Because of its long time adverse effects like breast cancer, thrombo-embolism, stroke, and heart ailments, HRT is not used for the treatment of osteoporosis (Rossouw, 2002).

### **5.2.3. Selective estrogens receptors (SER)**

Hormonal estrogen receptors are used for the treatment and management of postmenopausal osteoporosis. These pharmaceutical preparations do not have adverse effects like hormone replacement therapy. The fracture intervention trails on SER demonstrated that there is a significant reduction in the incidence of fractures of spine, hip and wrist fractures by 50% (Black, 1996).

### **5.2.4. Other Pharmaceutical interventions**

Parathyroid hormone, growth hormone, statins, fluorides, androgens, thiazides and calcitonins used for the treatment and for the prevention of osteoporosis in the high-risk groups.

### **5.2.5. Hip protectors**

The pooled data shows that there is a marginal reduction in the incidence rate of fracture among the users of Hip protectors (Parker, 2005).

### **5.2.6. Information based interventions**

The randomized controlled studies show information based interventions may prevent the moderate and minimal trauma fractures (Bliuc, 2006). By using this information, intervention methods in the high-risk group's subsequent fractures can be prevented

**Table 6. Prevention and treatment of post-menopausal osteoporosis**

Target group	Prevention		
	Primary	Secondary	Tertiary
	Population	Osteoporosis	Manifest osteoporosis
Lifestyle modification <sup>‡</sup>	+	+	+
Fall prevention <sup>‡</sup>		+	+
Hip protector <sup>‡</sup>		+	+
Calcium+vitamin D	+	+	+
HRT <sup>±</sup>		(+)	(+)
Bisphosphonates		+	+
Selective estrogen receptor modulators		+	+
Strontium ranelate		+	+
Parathyroid hormone(1-34)			+

Source: (Brixton , 2005) Current obstetrics and gynecology (2005), vol 15, Issue 4, p 251-255.

### 5.3. Tertiary prevention

#### 5.3.1. Surgical interventions

There are well-defined surgical procedures for the treatment like vertebroplasty, kyphoplasty for osteoporotic vertebrae (Frank, 2009). Other available interventions widely used for the treatment of osteoporosis fractures all over the world are internal nail fixation, Polymethylmethacrylate and calcium phosphate cements for osteoporotic hip fractures (Linder, 2009).



### **5.3.2. Post fracture care**

Pain management, psychotherapy, physiotherapy and fall prevention measures are the main measures for post fracture patients. There is need for special caregiver for the terminally debilitate patients.

#### **“Fracture Think Osteoporosis” (FTOP) Program**

This program includes the rehabilitation teams comprising of physiotherapy, health education to the geriatric professionals and psychological counseling. The Canadian health care system has been successfully implementing this program. The cohort study on post osteoporosis fracture patients showed an improvement in the care of the patients (Haaland, 2009).

#### **Psychosocial counseling**

Fractures lead to the lowering of the functional status, independence, social relationships and emotional well-being. These also lead to depression requiring psychosocial counseling.

#### **Quality circle technique**

To get the positive outcomes in the treatment and better management of osteoporosis, this tool is very useful (Abendroth, 2003).

### **5.4. Cost effectiveness for the screening procedures of osteoporosis: Screening with DXA**

The cohort on mass screening for osteoporosis with DEXA for postmenopausal women is cost effective and the detection is 100% to 50% (Richy, 2004).

**Treatment with bisphosphonates:** Studies claim that the treatment with the bisphosphonates is very cost effective and also shows that there is a gain of quality adjusted life years (Brecht, 2004).

**Hip protectors:** Studies show that use of hip protectors is not cost effective in the high-risk groups (Singh, 2004).

**Calcium and Vitamin D supplementation:** Prospective studies on calcium and Vitamin D supplementation show that there is 30-50% reduction of costs and fractures when compare with no treatment for osteopenic patients (Buckley, 2003).

## **5.5. Osteoporosis prevention and control in AP, India**

### **5.5.1. Primary care**

In India and the state of AP, there are no fixed policies and strategies for prevention and management of osteoporosis. However, other health policies and strategies on non-communicable diseases are indirectly useful for the prevention of osteoporosis.

**Anti smoking:** In India government introduced national tobacco control legislation "The Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003" (Tobacco legislation, who, India). This measure will help to prevent osteoporosis.

### **5.5.2. Secondary prevention**

In most of the country and the state of AP there are no screening facilities available for osteoporosis. Only limited number of services is available in the state capital. However, these services are available to the affluent societies. In the private health care, all drugs to prevent osteoporosis like bisphosphonates are available with high costs.

### **5.5.3 Tertiary prevention services in AP**

#### **5.5.3.1. Hospital services**

In the state at tertiary level, all osteoporosis curative services are available. Operation theater facilities for surgeries, trauma centers, drugs and physiotherapy facilities are available. In the cities DEXA machines are also available in the private health care with high costs. However, at the tertiary level there are no treatment schedules and protocols to treat osteoporosis cases. Because osteoporosis services at government and high costs in the private health poor people prefer to go to traditional health systems like bone setters for treatment and land up with serious health consequences.

#### **5.5.3.2 Osteoporosis clinics for elderly**

ICMR started osteoporosis clinics in all metro cities for elderly women. These centers focus on dietary intake, life style modification, and preventive measures to keep bone health and conduction awareness health camps (ICMR annual report, 2007). These services are also available to the better off people.

### **5.5.3.3 Rajiv arogyasri community health insurance scheme**

To help the people below poverty line, the government of AP introduced this insurance scheme in public private partnership. The osteoporotic fractures covered under this scheme and tertiary care service for osteoporosis are available for lower sections of people through this scheme (Arogysree trust, Government of AP).

However, with increase number of osteoporotic fractures, a strategy purely based on the hospital treatment will be very expensive and lead to increasing health expenditure and catastrophic costs.

## **CHAPTER 6. CONCLUSION AND RECOMMENDATION**

### **6.1. Conclusion**

This study identified that increased aging of the population, late development of peak bone mass, rapid urbanization, under nutrition, misuse of steroids in health care, early menopause, early hysterectomies, alcohol consumption, cigarette smoking, low consumption of dairy products, less consumption of animal protein, past exposure of chronic energy deficiency (CED) at adolescent age, poor perceptions about diseases are the main risk factors for osteoporosis in AP. Contributing factor for Osteoporosis in India is the lack of primary prevention strategies and poor facilities at primary health care level. People belonging to low socio economic sections often visit quacks and bone setters, who prescribe steroids.

The study identified that there is A high prevalence of osteoporosis in the both the cases and the controls. This study reviewed the risk factors and control methods for prevention and management of osteoporosis. The study also identified the mean age of fracture occurrence and the mean bone mineral density of the fractures.

- Prevalence of osteoporosis is very high in the low socio economic classes in the urban areas. This study also shows both men and women are equally prone for osteoporosis.
- In western countries, osteoporosis is occurring due to high protein diet and less physical activity but in India, it is happening among people who have a low protein diet and high physical activity.
- In the state of AP despite of self-sufficiency in agriculture, and existence of social safety net, 40% children are suffering with under nutrition. This is the precipitating factor for onset of osteoporosis.
- There is no program or policy on prevention and treatment guidelines about osteoporosis in the state and country.
- The study highlights the need of community based screening using low cost FRAX tools instead of costly DEXA screening.
- The study concludes that there is urgent need for prevention strategies and guidelines to combat the silent epidemic of osteoporosis in the AP state and India.
- The study confirms that fractures are happening 10 years earlier than the western populations.
- The study also confirms that In India"Osteoporosis time bomb" is ticking it requires urgent attention.

## **6.2. Recommendations**

### **6.2.1. To Ministry of health:**

**Population based prevention strategy:** In India Bone densitometries and costly drugs are not available to the majority of the population. There is a need for national campaigns to raise the bone mineral density through the behavioral modification. Studies show that an increase of 10% BMD of the population may reduce 20% of fractures in the population (Barret, 1998). A national intervention on anti-smoking campaigns, life style changes, and physical activity and high consumption of calcium rich foods need to be promoted.

**IEC:** The nation and state government should include balanced diet, physical activity, postmenopausal care and geriatric nutrition in national and state campaigns to sensitize the public about the prevention and its future consequences of osteoporosis.

**Development of infrastructure:** The ministry of health should allocate more funds and human resources to develop an infrastructure to support the prevention and control of osteoporosis. Government should also involve researchers, educators, individuals with osteoporosis and community members and health professionals to accomplish this. There is a need for shift from medical information to Programmatic approach towards self-care management. There is a need for a comprehensive medical information approach in both private and governments' initiation.

**Social safety net:** The government's social safety net should be extended to the urban poor and to the people in unorganized sector.

**Development of integrated health system:** Private Health care providers account for about 70% of health care in India. There is a need for public private integrated health care provision. All the scientific reports show that there is a high prevalence of osteoporosis in the low socioeconomic sections. Therefore, there is an urgent need to formulate labor rules to protect these groups from the risk of osteoporosis.

**Liaison between different health systems:** Along with allopathic and other alternative medicines, health care is very active in both private and public sectors. Government should coordinate and develop a common strategy to prevent osteoporosis.

**Training to Registered medical practitioners:** Because of high private health costs and non-availability of the osteoporosis care at primary and secondary level, people go to the traditional health care providers for services. In AP, unqualified medical practitioners are providing health care to the rural poor and lower social sections of the peoples. Department of health should conduct training camps and sensitize RMPs about osteoporosis and its consequences.

**Referral services:** There is a need for primary health care teams for health promotion for public and case identification of high-risk individuals and management and referral system to be developed.

**Community based Screening Strategies:** There are very few DEXA machines are available. These are available in the cities and with the private health care industry. The government should install DEXA machines at the district level for common public. There is a need for screening of high-risk groups like postmenopausal and elderly persons for prevention and management of osteoporosis. Government should give subsidies to the private health care providers for purchasing of DEXA machines. Because of limited resources, government should initiate community screening by using osteoporosis questionnaires or FRAX tool to identify the osteoporosis in high risk people.

### **Pharmaceutical industry**

Pharmacological interventions in the osteoporosis treatment are very expensive. Pharmaceutical industry should develop low cost antiresorptive drugs for treatment and to develop food based formulations for the prevention of osteoporosis. The ministry of health should negotiate with pharmaceutical companies to supply low cost drugs to the community.

### **6.2.2 Research organizations**

Research organization should develop evidence-based guideline for the prevention of osteoporosis and its management. There is an urgent need to develop national database on disease burden, hospital costs, prevalence and incidence of osteoporosis. There is a requirement for epidemiological and health economic research to estimate the health costs for future health planning on osteoporosis management. These institutes should work with International bodies like International Osteoporosis foundation and other health agencies to develop effective strategies. Because of non-availability and non-affordability of DEXA machines for bone mineral density estimations, research bodies should generate national data using WHO FRAX (Fracture risk assessment tool) method. By this method, we can estimate 10 years fracture risk with out the bone mineral density.

### **6.2.3. Hospitals and Medical schools**

All the district hospitals should create separate osteoporosis wards and out patient clinics for better treatment. To improve the knowledge and skills, updated treatment protocols on osteoporosis for the health professionals including continuous medical education (CME) programs should be organized. Medical schools should include medical curricula in the medical education.

**Osteoporosis clinics:** Government should start osteoporosis clinics with basic diagnostic facilities in cities for postmenopausal women and elderly. Government should extend this facility to the secondary level of hospitals to cover rural people.

### **6.2.4. Ministry of education**

Building of the peak bone mass at the childhood and adolescence is main factor to prevent onset of osteoporosis in the future. Department of education and department of health should develop a program to teach children, adolescents about the bone health. Education department should develop compulsory physical education program in all the schools. Education department should include topics of bone health in the curricula.

### **6.2.5. NGOs**

NGOs should sensitize the risk groups about the disease and prevention. NGOs should take active role in promoting active life styles and change of life styles. They should campaigns and promote consumption of dairy products, diet based calcium rich foods like Soya and other food products. NGOs should take part in promotion of non-vegetarian foods with out hurting the society sentiments.

**International NGOs:** The International NGOs like national osteoporosis foundation (NOF) should actively advocate the prevention strategies for osteoporosis and develop web based educated tools, country specific strategies for the developing countries.

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# Annexes

## Annex 1. Osteoporotic fracture DEXA scan report

**DIRECTOR  
NATIONAL INSTITUTE OF NUTRITION  
HYDERABAD, A.P. 500 007**

Telephone: 27008921

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Name: NARSIMHA.D Patient ID: FR-05 DOB: 01 June 1965	Sex: Male Ethnicity:	Height: 162.8 cm Weight: 42.1 Age: 40
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Referring Physician: DR. VEENA

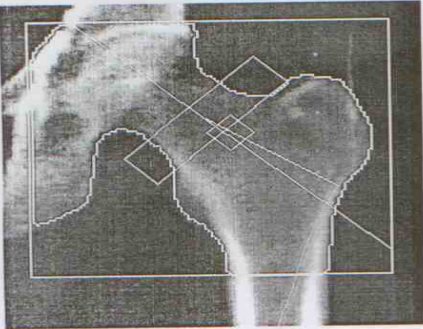


Image not for diagnostic use  
109 x 102

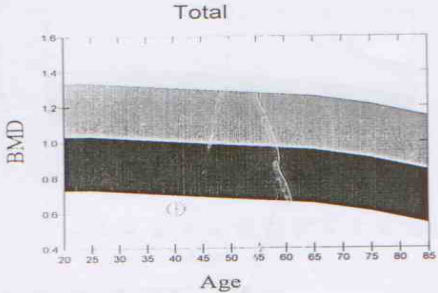
**Scan Information:**  
 Scan Date: 23 August 2005 ID: A0823050H  
 Scan Type: f Left Hip  
 Analysis: 24 August 2005 12:28 Version 11.1  
 Left Hip  
 Operator: U  
 Model: QDR 4500W (S/N 49184)  
 Comment:

**DXA Results Summary:** *See spine*


Region	Area (cm <sup>2</sup> )	BMC (g)	BMD (g/cm <sup>3</sup> )	T - Score	PR (%)	Z - Score	AM (%)
Neck	5.06	2.42	0.478	-3.3	51	-2.8	55
Troch	13.00	5.92	0.456	-2.5	59	-2.3	61
Inter	18.08	14.27	0.790	-2.2	66	-2.2	62
<b>Total</b>	<b>36.14</b>	<b>22.62</b>	<b>0.626</b>	<b>-2.7</b>	<b>61</b>	<b>-2.5</b>	<b>62</b>
Ward's	1.12	0.37	0.328	-3.2	42	-2.4	49

Total BMD CV 1.0%

**Physician's Comment:**



Reference curve and scores matched to White Male  
Source: NHANES



**Annex 2. X ray of Osteoporotic fracture patient.**



## Annex 3. SCORE Questionnaire

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### Appendix 1: Simple Calculated Osteoporosis Risk Estimation (SCORE) questionnaire

1. What is your current age?	<input type="text"/> <input type="text"/> years	Take the number in the shaded area, multiply by 3, and enter	<input type="text"/>
2. What is your race or ethnic group? (check one)	<input type="checkbox"/> Black <input type="checkbox"/> Caucasian or Asian <input type="checkbox"/> Native Canadian / First Nation or Other	Enter 0 Enter 5 Enter 5	<input type="text"/>
3. Have you ever been treated for or told you have rheumatoid arthritis?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, enter 4 [if no, enter 0]	<input type="text"/>
4. Since the age of 45, have you experienced a fracture (broken bone) at any of the following sites?			
Hip	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, enter 4 [if no, enter 0]	<input type="text"/>
Rib	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, enter 4 [if no, enter 0]	<input type="text"/>
Wrist	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, enter 4 [if no, enter 0]	<input type="text"/>
		Subtotal	<input type="text"/>
5. Do you currently take or have you ever taken estrogen? (Examples include Premarin, conjugated estrogens, Estraderm, Estrace, Estinyl, Ogen, Estracomb)	<input type="checkbox"/> Yes <input type="checkbox"/> No	If no, enter 1 [if yes, enter 0]	<input type="text"/>
<i>Add SCORE from questions 1 to 5</i>			<b>Subtotal</b> <input type="text"/>
6. What is your current weight? (convert from kilograms)	<input type="text"/> <input type="text"/> <input type="text"/> pounds	Take the numbers in the shaded area and <b>subtract</b> from subtotal	
			<b>Final SCORE</b> <input type="text"/>

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