"RELIABILITY OF RADIOLOGICAL INDICES IN COMPARISON WITH DUAL ENERGY X-RAY ABSORPTIOMETRY IN DIAGNOSIS OF OSTEOPOROSIS –A ONE YEAR HOSPITAL BASED COMPARATIVE STUDY"

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LIST OF ABBREVIATIONS

BMD	-	Bone Mineral Density
BMI	-	Body Mass Index
DEXA	-	Dual Energy X-ray Absorptiometry
H/O	-	History of
HRT	-	Hormone Replacement Therapy
Ht.	-	Height
IP No.	-	Inpatient Number
Lt	-	Left
OP.No.	-	Out Patient Number
pDEXA	-	Peripheral Dual Energy X-ray Absorptiometry
PTH	-	Parathyroid Hormone
QCT	-	Quantitative Computerized Tomography
RA	-	Radiographic Absorptiometry
ROM	-	Range of movement
Rt	-	Right
SERM	-	Selective Estrogen Receptor Modulator
Sl No.	-	Serial Number
USG	-	Ultra Sonography

Wt.	-	Weight
CTI	-	Cortical Thickness Index
AP	-	Antero-posterior
Lat	-	Lateral
CCR	-	Calcar to canal ratio

ABSTRACT

TITLE:"RELIABILITY OF RADIOLOGICAL INDICES IN COMPARISON WITH DUAL ENERGY X-RAY ABSORPTIOMETRY IN DIAGNOSIS OF OSTEOPOROSIS –A ONE YEAR HOSPITAL BASED COMPARATIVE STUDY"

INTRODUCTION:

The term osteoporosis stands for Osteo- bone and poros- structure with tiny holes. It is a process wherein, the microstructure , quality and the mineral density of the bone is compromised or lost. This change occurs in a tranquillity, progressively and symptomless until the fracture occurs. It is a regularly noticed disorder of the osseous skeletal system occurring in the geriatric age and is often unrecognised or undiagnosed. It projects a dominant issue related to health in the community in developing country like ours –India. Osteoporosis results in serious complications like hip and spinal bone fractures. Hip fractures usually have an atypical presentations like subtrochantric fractures , peri-prosthetic fractures and require surgical fixation whereas vertebral involvement present as chronic back ache , wedge compression fracture , deformity (Hunch back) etc. Hence diagnosis and early treatment of osteoporosis is of utmost importance. DEXA Scan is the best, unambiguous and meticulous modality to measure the bone mineral density known by far till date[1]. The fracture risk can be assessed by clinical evaluation of risk factors and by evaluation of mass of bone by physical techniques.The present study compares the reliability of radiological indices versus gold standard DEXA scan in the diagnosis of

Osteoporosis. So that the radiological indices can be used to diagnose osteoporosis in the peripheral setup in a cost effective manner.

AIMS AND OBJECTIVES:

1. To assess the reliability of radiological indices in comparison with DEXAscan in diagnosis of osteoporosis

2. Cost effectiveness of radiological indices in diagnosing osteoporosis.

MATERIALS AND METHODS:

A one year comparative study was conducted in the Department of Orthopaedics, KLEsDr.Prabhakar Kore Hospital and MRC, Belagavi.

80 patients presenting to OPD / IPD of Department of Orthopaedics, fulfilling the inclusion and exclusion criteria were enrolled in the study. After getting an written informed consent, the patients were subjected to DEXA scan and a plain radiograph of either of the hip joint with full length femur in AP and Lateral views. Subsequently, the Singh's Index, CTI(AP and Lateral) , CCR were measured and compared with the standard DEXA scan.

RESULTSand Conclusion:

The obtained data was statistically analysed using SPSS software. The mean, Standard deviation, correlation between DEXA scan and Radiological Indices by Spearman's co-efficent, Level of agreement(Kappa) were calculated. A cut off of 0.43 for both CTI (AP & Lateral) and 0.50 for CCR was deduced. There was a Significant correlation seen with DEXA scores using Spearman's Rank Co-efficient($p<0.0001$) and a Substantial level of agreement using Kappa statistics. With greater Sensitivity

and specificity,positive predictive value CTI(lateral) is more reliable compared to other indices in this study. Though there was a Significant correlation of Singh's Index with DexaScores, due to its limitations of reproducibility, observer bias , technical limitations with the Radiography , and application to a larger population , it is concluded that Singh Index is not reliable in diagnosis of Osteoporosis.Radiological indices are both Reliable and cost effective in the diagnosis of Osteoporosis

KEY WORDS:

Osteoporosis, DEXA scan, Radiological Indices, Cortical Thickness Index.

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INTRODUCTION

The term osteoporosis stands for Osteo- bone and poros- structure with tiny holes. It is a process wherein, the microstructure, quality and the mineral density of the bone is compromised or lost. This change occurs in a tranquillity, progressively and symptomless until the fracture occurs[1] .

It is a regularly noticed disorder of the osseous skeletal system occurring in the geriatric age and is often unrecognised or undiagnosed. It projects a dominant issue related to health in the community in developing country like ours –India[1].

Osteoporosis is a condition wherein "there is generalised demolition in bone mass and micro-architectural disfigurement of bone structure, with a simultaneous decrease in bone strength and increased probability of a fracture" [1, 3]. The definition suggests that the Bone Mineral Density (BMD) is a important parameter in detection of Osteoporosis[4].

As per WHO (World Health Organisation),for detection of osteoporosis on the level of BMD T-scores(i.e in comparison with T-scores of average young adult) are as follows-

1. Normal- equal to or above -1 standard deviation
2. Osteopenia- -1 standard deviation to -2.5 standard deviation
3. Osteoporosis- -2.5 standard deviation and below
4. Severe osteoporosis (established osteoporosis)- BMD below -2.5 standard deviation with atleast one low energy trauma fracture [5].

Osteoporosis results in serious complications like hip and spinal bone fractures. Hip fractures usually have an atypical presentations like subtrochantricfractures,peri-prosthetic fractures and require surgical fixation whereas

vertebral involvement present as chronic back ache, wedge compression fracture, deformity (Hunch back) etc[1].

Osteoporosis is mainly a condition of post menopausal women but may be seen in both the sexes due to various underlying conditions. It is seen that the mortality in an osteoporotic hip fracture for female in her lifetime is much more greater than with breast cancer[1,2].

Studies suggest that about 25percent of patients having fracture of Hip need continuous care and around Fifty percent of patient will only walk with assistance. There is 20% higher mortality than for average normal healthy individual with greater incidence in men than women[6].

As the age progresses, there is reduction in calcium absorption from the intestines, and thus with reduced calcium supplementation along with decreased absorption leads to major decrease of dietary calcium resulting in osteoporosis in the elderly[1].

In India, the highest incidence is at 50-60years of age, when compared to western countries it is around 70-80years[8]. By year 2050, it is expected that the hip fractures as a resultant of osteoporosis would exceed six million[9].

DEXA Scan is the best, unambiguous and meticulous modality to measure the bone mineral density known by far till date[1]. The fracture risk can be assessed by clinical evaluation of risk factors and by evaluation of mass of bone by physical techniques.

OBJECTIVES

1. To assess the reliability of radiological indices in comparison with DEXA scanin diagnosis of osteoporosis

2. Cost effectiveness of radiological indices in diagnosing osteoporosis

REVIEW OF LITERATURE

History:

The process of bone remodelling i.e formation of new bone and resorption of bone was described by an English surgeon John Hunter in the early 18th century. This process has a major contribution in osteoporosis. This process was not known or been described even after 100years of his death[11] .

Another English surgeon Astley cooper noticed an increased threat of fracture in elderly individuals due to low bone mineral density and hence for the first time recognised Osteoporosis in 1800's[11].

Similar recognition and descriptions were given by a pathology doctor, Jean Georges Chretien Frederic Martin Lobstein in 1830's. In the study of sample of bones of some patients, he noticed difference in the bone architecture with large holes. Hence quoted the term "Osteoporosis" looking into the porous nature of the bone. But the pathologist was not able to describe the pathology causing the porosity nor the symptoms of osteoporosis[12].

In 1906, Jacob Erdheim , an Viennese pathologist noticed pea sized glands enlarged in three patients and conducted a series of experiments in rats by removing the parathyroid gland. In his experiment he noticed that on removal of parathyroid glands the teeth calcium content in rats was reduced. Thus concluded the relationship of parathyroid gland and calcium [14].

In 1925 a Scientist from Canada, biochemist, James B. Collip, in his research and experiments found a similar active extract that elevated the calcium content in bloodstream. The extract subjected to purification, resulted in a hormone called parathyroid. This experimentation gave a new theory, that parathyroid hormone leads

to increase in serum calcium levels when the levels of calcium falls in the same and maintains homeostasis[14].

Albright gave an revolutionary theory in 1940 about alliance among estrogen and BMD. He proposed that estrogen helps deposition of calcium on the osseous skeleton and this calcium is channelized to the blood stream during gestation and breast feeding phase to makeup for excess necessity of baby and mother. With the decline of this hormone during menopause there is less bone deposition and more break down of the bone to maintain the calcium homeostasis, thus leading to porous bone. He so named it as "Postmenopausal Osteoporosis". Further, with series of his experiment with injection Estrogen, concluded that there was an increase in calcium reserve of the body mainly in the bones. He hence not just proved but also recognised Postmenopausal Osteoporosis and for the very time described the treatment for the same[13].

In the 1960s, of Herbert Fleisch found a newer element in homo-sapien blood and urine that did not allow calcium salts to form in a lab setup. It was found that the element was "Pyrophosphate". Fleisch noticed this property of pyrophosphates and its use in treatment of numerous bone diseases, also osteoporosis. This lead to discovery of drugs called "Bisphosphonates" by the scientist in association with drug companies. Alendronate and Risedronate are being widely used from 1996 and 2000, for treating osteoporosis in women attained menopause[14].

Embryology of proximal Femur:

The Hip joint begins to evolve around 49 days of gestation. Within the primitive limb bud[mesenchyme] there develops a cleft. This cleft has precartilagenous cells which transform into femoral head and acetabulum which is absolutely cartilaginous around 77 days of pregnancy. The contour of acetabulum is established by femoral head contained within acetabular cavity.

The development and growth of proximal femur is complex. In early life, the upper femur is completely cartilaginous in femur head and the trochanters. The development occurs through amalgamation of appositional growth in proximal femur and epishyseal growth at the junction of proximal femur and shaft femur.

ANATOMY

The Skeletal Anatomy:

The proximal femur consists of spongy bone, invested by a thin layer of compact bone. The trochanteric region consists more of spongy bone.

Trabecular System: fig 1

During nineteenth century[1838], **Ward** elucidated the trabecular pattern of femoral head. The trabeculae are oriented along the lines of stress. There are five normal groups of trabeculae as described by Ward.

Primary Compressive Trabeculae: These are the strongest trabeculae, extending along medial cortex at base of neck of the femur to subchondral bone of the superior and medial part of head of femur.

Primary Tensile Trabeculae: These commence from the inferior area of the foveal part along the head and superior aspect of the femoral neck onto the greater trochanter, to the lateral cortex.

Secondary Compressive Trabeculae: These extend from the medial femoral cortex in the region of the lesser trochanter towards the greater trochanter.

Secondary Tensile Trabeculae: These extend from the lateral femoral cortex, inferior to the primary tensile trabeculae towards the middle of the femoral neck.

Greater Trochanteric Trabeculae: These extend from the superior border of the greater trochanter to its base . The space bounded by the primary compressive and tensile trabeculae and the secondary compressive trabeculae is known as **Ward's Triangle**[14].

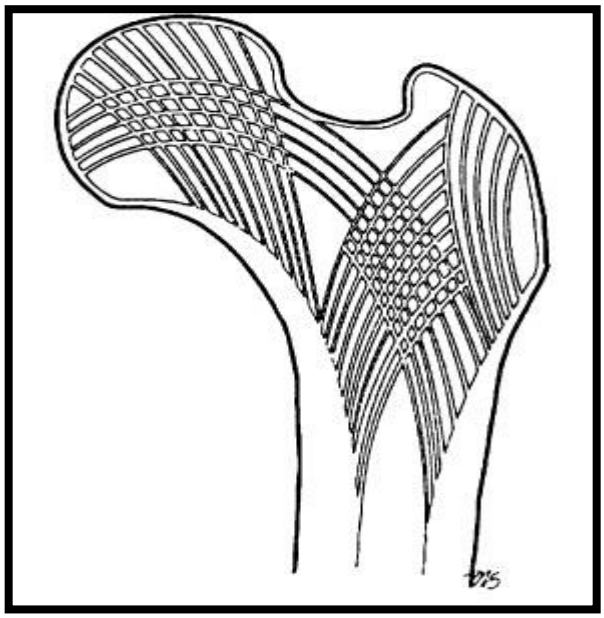


Fig 1: Trabecular pattern of the femur

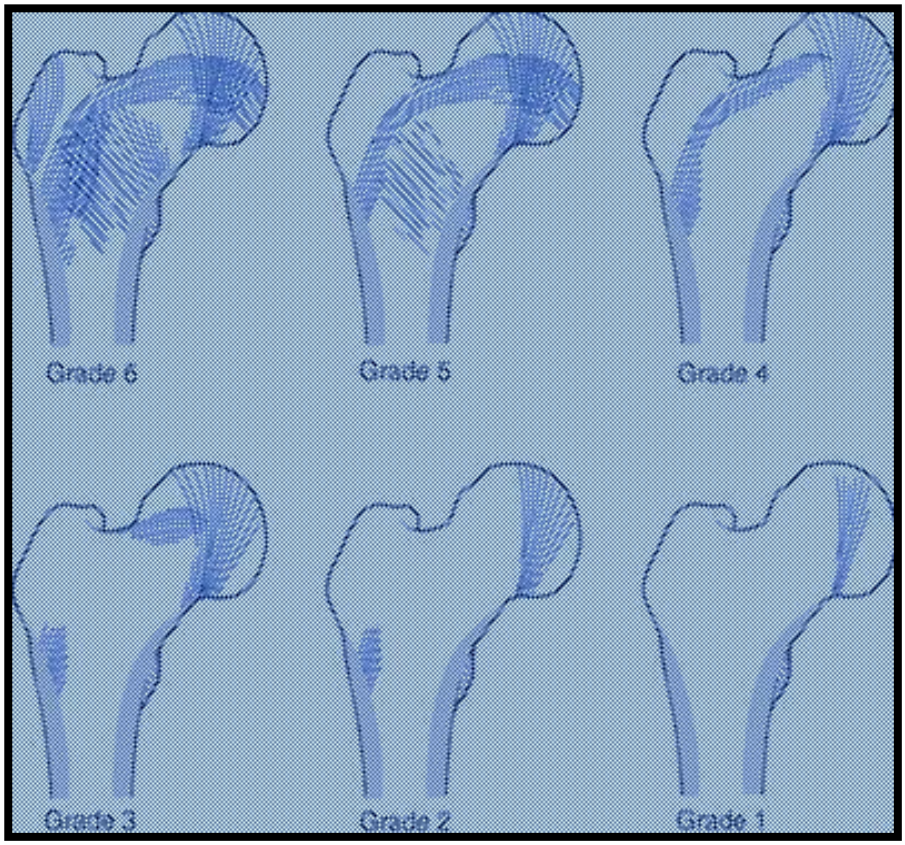


Fig 2 : Singh's Index

Singh M. Introduced approach to ascertain the extent of porosity of bone byanalysing the trabecular pattern at proximal end of femur bone evident on plain radiographs. The degree of osteoporosis is graded from 1 to 6.

Singh's Index:

Grade 6- Entire trabecular patterns are evident, also upper part of femur appears entirely engaged with cancellous bone.

Grade 5- pattern of the 1^0 tensile and compressive trabeculae is more noticible. Ward's triangle is more evident.

Grade 4- 1^0 tensile trabeculae are significantly decreased but can still be tracked from lateral cortex to proximal aspect of neck of femur.

Grade 3- Fragmented pattern of the 1^0 tensile trabeculae facing the greater trochanter. This type suggests guaranteed osteoporosis.

Grade 2- Only 1^0 compressive trabeculae appear proud; the rest of trabeculae are almost disappeared.

Grade 1- 1^0 compressive trabeculae are also drastically decreased in number and are very less or not evident[16].

RISK FACTORS

Peak Mass of Bone:

For good osseous health and for prevention of osteoporosis, having a good bone mass is very important. Peak mass of the bone is the bonetissue as an outcome of the skeletal maturation17. The results of osteoporosis show up late in life, but the process begins in childhood or adolescence. The Mass of bone peak is a crucial parameter in pathogenesis of porosity of bone. Around 40percent of mass of bone is formed in childhood or adolescence[18]. A study done in INDIA showed that the peak mass of bone is achieved at the age of 25years in males and 28 years in females , which are at a lower range when compared to the healthy young individual in western countries[19].

Genetic Factors:

Genetic predisposition has a major role in Bone mineral density in early age (20-30years) and in post-menopausal Bone mineral density loss[20]. It is shown to have a 50% chance of modulation in Peak bone mass, bone geometry, bone strength, and bone architecture[21].

There are few studies which indicate that the genetic factors like D-receptor gene, Estrogen receptor gene, Collagen receptor gene have 75% role in deciding the peak bone mineral density[22]. Studies suggest that the negro females had greater mineral density of bone and had less chances of hip fracture compared to other population. With the history of hip fractures in the maternal family of women there was twice the risk in women for hip fractures than women without such history[23]. Indian Studies showed Receptor gene for VitD[VDR] polymorphism,

Estrogenreceptor Alpha polymorphism gene are associated with decreased bone density in Indian women after menopause[24].

Gender and Sex:

About 30-50% women and 15-30% men are suffering from osteoporosis all over the world in a given time[25]. In females , the incidence of fractures due to porosity of bone are significantly high, in contrast to incidence of heart attack, Stroke, Cancer of mammary glands in females across the world[26]. Men are three times less at risk than women for osteoporosis in a lifetime[27].

Age:

With the advancement of age , the risk of osteoporosis and risk of fracture in both sexes increase equally[28]. Bone mineral density and age are inversely related ,i.e with the increase in age the bone mineral density falls exponentially. With the increase in geriatric population in an developing country like INDIA, due to increase of longevity and standard of living, the population pyramid shows raise in the above fifty years population in both men and women and also increase in threat of osteoporotic fractures.

Menopause:

In woman, osteoporosis after menopause is the commonest and causing more morbidity and mortality[28]. Globally, the average of women attainting the menopause is around 52years whereas in INDIA it is comparatively less as more number of hysterectomy were reported in urban areas[29]. With the duration of menopause of more than 5 years showed a greater risk of osteoporosis.

Parity & lactation:

Parity and lactation have a profound outcome on mineral density of bone as per studies from various countries like Morocco,Vietnam, and Korea[31].South American studies showed higher incidence of osteopenia and osteoporosis in nulliparous women[32]. Prolonged breast feeding , time since amenorrhea and weight before pregnancy have role on bone mineral density and studies show prolonged lactation leads to the loss of calcium, resulting in reduced Mineral Density of bone [33].

Medical Factors:

Gastrointestinal diseases (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[34]. Steroids usage is rising in routine treatment schedules in India. Studies showed increased usage of steroids may end up in decreased loss of osseous resorption leading to raised fracture risk[35]. The recent meta analysis from Cochrane show use of steroidal contraceptive like Depot medroxyprogesterone acetate (DMPA) will reduce the bone mineral density and increase risk of fractures[36].

Nutrition factors:

Vitamin D: Vitamin D has a critical role in calcium homeostasis in the body, in turn deciding the bone mineral density[37].In countries of Asia like that of India, China ,Japan and Middle East, majority of the population have inadequate Vit D[38]. Studies revealed that in elderly with low levels of vitamin D there was increase in

incidence of hip fractures. With low quantities of Vit D, there is elevation of parathormone production leading to escalated bone turn over and low bone mineral density[39]. The study shows the prevalence of Vitamin D deficiency in the school children of North India is pronounced[41]. Recent study show there is awidespread Vit. D deficiency globally, including India and is responsible for osteoporosis fractures and going to be major public health problem[42].

Calcium : Cross sectional studies showing higher intake of calcium in the childhood and adolescent age may increase the bone mineral density in children, adolescent and young females[43]. Dietary Calcium deficiency and less (BMI) in lean men and women, lead to the reduction in Bone Mineral density[44]. Study from India shows in the low socioeconomic groups the Calcium intake is only 300 mg, which is 700mg less than the required amount[45]. In India about 40% people from Low socio economic groups suffers with Chronic Energy Deficiency and have inadequate energy, protein Calcium and other micro Nutrients[46]. Many medications like Diuretics, anti Consultants, Non Steroidal anti Inflammatory medications, Corticosteroids, Immunosuppressive medications and some antibiotics will impair the Calcium absorption[47].

Vegetarianism: Indian study showed population on veg diet have 50percent risk ofosteoporosis and 98.82percent population have osteopenia[48]. Vegetarian food has less calcium, less absorption of calcium and poor bioavailability, this may be the reason for reduced mineral density of bone and risk for fractures due to porosity of bone among the vegetarians[49]. People with vegetarian food habits were at a greater risk for porosity fractures, especially among Indian and Iranian subjects.

Physical activity:

Several cohort studies showed with increasing age and decrease in physical activity, there was significant decrease in mass of osseous structure and elevated danger of osteoporotic fractures[50]. Studies have shown that with weight bearing exercises there was a positive response on mass of osseous skeleton, peak mass of osseous structure, reduction in osseous loss and mechanical stress[51]. Studies from China shows physical exercise by postmenopausal women have a substantial reduction in BMD loss and have positive health effect[52].

Another study conducted in India showed that low socio-economic status had poor bone health, even with good physical activity due to poor nutriton[55].

European vertebral osteoporosis study (EVOS) studies shows high physical activity leads to the fractures in men[53]. Another study show high physical activity is more associated with hip fracture than the other fractures[54].

Lower body weight and Body mass index:

Studies revealed that in person having lower body mass index, there is increase risk of osteoporosis and osteoporotic fractures[56]. Epidemiological studies shows low body weight is the one of the main determinant and risk factor for hip fractures[58]. European studies shows Individuals with BMI less than 19kg/m^2, are at risk of Osteoporotic Hip fracture[59].

Low exposure to sun light:

Various studies have proven a direct and strong association of exposure to sunlight and hip fractures in elderly population (> 50yrs)[59]. Vitamin D is obligatory

for osseous well being and had an influence on growth and development of children and its deficiency leads to increased bone turn over, enhanced bone loss and fracture risk[60].

Smoking:

India stands Third in list of largest production of tobacco in the world. According to NFHS2 data the prevalence of smoking among men above 30years is 41.2% and 18.2 % in women above 30 years[62]. Large cohort study on smokers and non smokers followed for 12 years showed, women who smoke more than 25 cigarettes or more had 1.6 times risk for hip fracture than the (95% CI,1.1-2.3) non smokers[63]. Studies identified strong association between cigarette smoking and risk of Osteoporosis, which is considered as Public health problem and showing deficit in spinal bone density of 1.5% and Hipbone density 1.1% in men and in women of 1.5% and 0.4% respectively.[64] Prospective and cohort studies shows smoking will decrease the Mineral Density of osseous structure and leads to the threat of Osteoporosis fractures for both males and females and also studies demonstrating that quitting smoking may help to reduce the fractures[65]. Studies showed smokers have lower retention capacity of calcium and leads to bone loss[66]. Cigarette smoking in women reduces the Bone mineral Density and leads to early stoppage of menstrual cycle, decreased weight of body and leads to metabolic fragmentation of exogenous oestrogen in women and causes fractures in women[67]. Epidemiological studies showed cigarette smoking is the independent parameter for fractures of hip in both sexes[68].

Geographical Variation:

Profound geographical variation is noted in the Mineral density of osseous structure as also the incidence of porous bone fracture vary substantially related to geographical areas[69]. 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[71]. Lower life expectancy may be a reason for lower incidence rates in developing countries[72].

The incidence of fractures of hip due to porous nature of bone is more in urban areas in comparison to rural areas attributing to sedentary lifestyle and unhealthy food habits and low bone mineral density[73]. 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[74]. Study from Vietnam showed in premenopausal women, prevalence of porosity of bone was much pronounced in urban areas than the rural areas[76].

Scientific reports describe osteoporosis is the outcome of the modernization and the incidence of osteoporosis fractures are more in urban than the rural areas[77].In China and other developing countries, bone mineral densities are different between urban and rural population because of rapid transition towards urbanization[78]. Because of rapid urbanization in Hong Kong and other parts of Asia , lower incidence of fractures of hip rates were reported in villages than the city areas[79].

Secular trends:

Increase of life expectancy all over the world and increase of old age population, increase of monetary and health expenditure of the osteoporosis may be doubled in days to come[80]. There is negative impact on mass of osseous structure or the risk of falling is influencing the rise of fractures in successive generations of the elderly[81]. In developing countries , like Hong Kong Osteoporosis fractures cases are rising but in western countries it reached plateau[82]. 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[83]. There is an increasing trend of osteoporotic fracture cases in India andother countries. Because ofgood screening procedures, availability of good diagnostic techniques , the future projections due to osteoporosis can be estimated[84].

Ethnicity:

The bone mineral densityvaries between different ethnic groups. Blacks had a more BMD, the Caucasians and Asians had a less bone mineral density[85]. Fractures rates are lower in the blacks and Asians, whereas whites and Hispanics had higher fracture rates[86]. Osteoporosis hip fractures are more in Caucasians than the Black and Asians[87].

Review of Literature:

In a study by Sridhar et al using visual X-ray for assessment of bone mineral density, reported that 6 out of 100 healthy Indian population below age of 50 years had an evidence of osteopenia[88].

In another study, by Khanna and Bhargava , stated that on radiological study of bones conducted on 60 asymptomatic Indians revealed that 13% of them aged between 10-70 years showed osteopenia[89].

Pande et al from Nagpur in his study for the very first time,established a reference database of mineral density of osseous skeleton using a digital Radiogram in Indian - Men and Women, which involved 177 men and 261 women. It showed that approximately 50% females and 36% Men above 50years had low bone mass[90].

To analyse the prevalence of osteoporosis using a quantitative Ultrasonography of calcaneumAcharya et al reported that among 1136 post-menopausal women from both Rural and Urban areas falling between 40 to 60 years age, the prevalence was 15%. Similarly he evaluated the pre-menopausal and noticed that the prevalence of porosity of bone in urban women was remarkable in comparison with the rural women. But he found that in post menopausal women the prevalence of porosity of bone is greater in rural women than urban women[91].

Sharma et al screened 158 women from city of Jammu using heel QUS. It was found that 20.25percent population had osteoporosis and 36.79percent population had osteopenia. Majority of osteoporotic and osteopenic individual were females between 55-64 years of age. Above 65 years, it was observed that the incidence of osteopenia

or osteoporosis was almost 100percent. Dietary habits and religion had impact on resultant of osteoporotic and osteopenia score[92].

These studies and Data were based on regular conventional X-ray radiographs, before the advent and installment of first DEXA scan machine in INDIA in the year 1997.

Anburanjan et al provided a data based on their study on mineral density of osseous structure in proximal femur in South Indian females. It stated that the rate of mineral density loss at 65 years of age for the , trochanter, femur neck , intertrochanteric area, entire hip and also the Ward's triangle were 0.84%, 0.91%, 0.72%, 0.78%, 1.66%. per annum respectively[94].

A study was done in South Indian Senior citizen women by Usha G et al to correlate BMD with risk factors. The study suggests BMD value of 0.72 at the femoral neck as a fracture threshold. Also suggested that there is an inverse co-relation with Increase in the age and years after menopause on BMD[95].

A study was conducted in an urban region of south India by Paul TV et al to know the prevalence of osteoporosis in mobile post-menopausal women . He evaluated 150 women using a DEXA scan and comparing it with calcium nutrition and Vit. D levels .It revealed that the risk of Osteoporosis at Vertebra[lumbar] was 48percent , femur neck was 16.7percent and at any other site was 50percent [96].

A study done by Kadam et al. to know the prevalence & relative significance of risk factors for low mass of bone in urban Indian women above 40 years of age showed Bone mineral density measurement at Hip, wrist and Spine were substantially low($p < 0.001$) in menopausal women when compared to women who

have not attained menopause. It was noted that the osteoporotic changes along the lumbar spine was greater with the prevalence rate of 25.8 percent in women who have attained menopause, on the other hand it was seen that in pre menopausal women the prevalence rate of osteopenia was high 44.3percent. 41.8percent women after menopause and 54.5 percent premenopausal women were deficient of Vitamin D. Lumbar spine mineral density and Sun Index correlation was found to be of very little significance[98].

A study done by Veena .et al to assess BMD of women from a Low Socio-economic group and correlation of it with nutritional status. Two hundred eighty nine individuals(women) ranging between 30-60 year age were assessed for BMD by Dual Energy X-ray absorbtiometry Scan revealed that 29percent women had an evidence of osteoporosis at femur neck. There was decrease in mineral density of bone after 35years of age in vertebra[lumbar] and neck of femur. It was also noticed that with gain weight of the body, there was significant raise in the mineral density of osseous skeleton in the entire body and also supplementation of calcium was one the factor for the same[99].

Marwaha R K et al. in their study to determine bone mineral density in Urban areas, evaluated 1600 individuals residents of Delhi .The aim of the study was to correlate and compare central DEXA scan and Peripheral DEXA scan in detection of Osteoporosis and also for bone mineral metabolic parameters. Osteoporosis detected in 24.6percent males and 42.5percent females with overall incidence of 35.1percent. Osteopenia was seen among 54.3percent males and 44.9percent females with an overall osteopenia in 49.5percent subjects. A negative correlation was seen between Bone mineral density (BMD) and Parathorome levels. BMD at forearm and

calcaneum, measured using pDXA, showed strong positive correlation with BMD measured by central DXA, pDXA(BMD of Calcaneum and Forearm) showed a substantial positive correlation with Central DXA(BMD at Spine) with 55percent specificity , sensitivity of 88percent, positive predictive values(PPV) of 52percent and negative predictive value(NPV) of 89 percent[100].

Mehta et al in their study to determine Bone mineral status in immigrant Indo-Asian women, found that the bone mineral density of Indo-Asian women was much lower when compared to same age Caucasians at the spine . But it was noted that there was no difference when BMAD was assessed , which is a volumetric Density of the bone. He also suggested that due to size related artefacts there may be low bone mineral density values in Asians[102].

A study by John et al. in Newyork , done for determination of the correlation of radiomorphometry to the severity of osteopenia as deduced by Total body neutron activation analysis and photon absorptiometry. The radiographic techniques used were Metacarpal index, the femoral score, total peripheral score , biconcavity index , femoral trabecular pattern. It revealed there was a remarkable co-relation among the regional bone mass ratio and metacarpal index and femoral score. The correlation was better for total peripheral score[103].

Many Investigators studied the reliability of Singh's Index and found no significant correlation. In a study conducted by V C M Koot et al. for ascertaining the reliability of Singh's Index in 1966, Six different evaluators were assigned to assess the radiographs and grade the same according to the Singh's Index grading. It was seen that there was a very low interobserver variations(kappa=0.15 -0.54) and

intraobserveracceptance(kappa =0.63-0.88) had strong reliability and therefore, no significant correlation between Singh's Index and density measurement of bone[104].

Similarly,Salamat et al. analysed the plain X-ray films of 72 individuals suspected of having osteoporosis with 3 examiners. The results suggested that there was significant disagreement between the grading of the Singh Index by the three observers and the variation was large. He also noticed that no relation between density of bone and Singh Index[105].

Also numerous studies have been conducted to assess the fracture risk , bone mineral density and diagnosis of osteoporosis by many different investigators . Lopamudra et al studied plain Xray films of pelvis of 168 to anticipate risk of getting an fracture due to low mineral density of bone using morphometric parameters of femur-proximal end. He analysed neck shaft angle of femur , axis length of hip , axis length of neck of femur and compared with the Dexa Score of femur neck. It was found that there is a very good correlation with neck of femur bone density and morphometric characters of femur –proximal end[106].

Ahmad FakhriZadeh et al. evaluated the accuracy of cortical thickness of tibia for diagnosing porosis of bone in relation to the benchmark Dexa scan, 62 people were evaluated and the Tscore was found to be in good correlation with cortical thickness of tibia, and concluded that this method can be used for diagnosing porosis of bone[107].

Andy K.S.yeo did a retrospective study in 112 patients of femur neck fractures to look for the status of vitamin D and also to check the reliability of indices on radiographic films of proximal femur as an indicator of mineral density of bone , in which he assessed the cortical thickness index of femur in both AP and Lateral views

on plain radiograph and also calcar to canal ratio , he compared these indices with the DEXA Tscores. He concluded that there is a substantial correlation between the indices and the DEXA Tscores and are reliable in diagnosis of osteoporosis[108].

BMD Assessment

Mineral density of bone assessment is a prime parameter in detecting osteoporosis and also mapping the treatment and avoiding fracture occurrence. Numerous methods are in practice, utilised for evaluating mineral density of bone. Most commonly used on OPD basis and also on large scale screening is the USG(Ultrasonography), others are Radiographic-Absorptiometry, [SXA]Single-Energy XRay Absorptiometry,[QCT]Quantitative-Computed-Tomography. Hip and Lumbar spine are most frequently used areas for assessment of central mineral density of Bone whereas, peripheral-mineral density of bone areas are, Calcaneum, Distal radius and the both bones of forearm. According to WHO guidelines and mineral density of bone values cut-off for detecting porosity of bone, Dual-Energy XRay Absorptiometry[DEXA] is always found reliable and is a bench mark investigation. DEXA of the hip and spine is the gold standard for baseline BMD determination and follow-up measurements[1-3].

Mineral density of Bone is measured in values of T-score. The patient's value of T-score is compared in terms of [SD] Standard-Deviation with normal average adult T-score for mineral density of bone[1-3].

Similarly, The Z-score for mineral density of bone is also calculated. This score is obtained by comparing the average mineral density of bone in terms of Standard-Deviation with average mineral density of bone of similar age and sex of normal individual. By far this score is never utilised in defining the extent of porosity

of bone, as it does not show the rising pattern of prevalence of porosity of bone with increase in age[1-3].

Mineral density of bone evaluation is a cardinal parameter in identifying porosity of bone and also in knowing the chance of fracture due to low mineral density of bone. On the grounds of mineral density of Vertebrae, The World-Health-Organization [WHO] describes reduced mass of bone and porosity of bone, to recognise the people at verge and assist in screening the population. Tscore cut-off is used in detecting porosity of bone. It is rational and logical to tag a individual with Osteoporosis, when the mineral density of the bone is reduced and has a frailty fracture of the bone[1].

Guidelines for Mineral Density of Assessment:

Numerous Non-government and Government establishments suggests that all women after Menopause should subjected to assessment of mineral density of bone as they are at an higher threat of porosity of bone. The N O F[National-osteoporosis-Foundation], U.S- Preventive- Services –TaskForce[USPSTF], International Society for Clinical Densitometry[ISCD] suggests that mineral density of bone of all the females above the age of 65 should be checked in every Caucasian female population . Among females who have attained menopause and have a past of frailty fracture of bone, evaluation of mineral density of bone is not necessary in detection of osteoporosis. Here, the mineral density of bone assists in looking for the reciprocation of the treatment and evaluating the risk of fracture[4-5].

Dual-Energy X-Ray Absorptiometry [DXA or DEXA][1]

The Measurement of density of bone is a paramount method in determination of osteoporosis. This helps in perfect and valid reproduction of evaluation of quantity of mineral in the bone and also empower the identification of osteoporosis prior to the fracture due to fragility. DEXA Scan of axial skeleton is a benchmark and investigation of choice, with reference to all the available investigation methods in detection of porosity of bone and assessment of Mineral density of bone.

DEXA utilizes a pair of Xray tubes which project the beam at discrete level of energy, and scans the area of importance and evaluates the depression of the beam as it courses from the osseous structure. The beams with less energy will have pronounced depression in comparison with beams with more energy. The Xrays are more depressed by an osseous structure in contrast to non-osseous structure. On grounds of this property, modification in non-osseous structure can be done, as it is significant because the soft tissue density or amount circling the Spine and the Hip will differ from person to person.

Mineral density of bone measurement at Hip

The proximal end of the femur bone is made of a very divergent amounts or proportion on cancellous osseous structure in contrast to the axial skeleton which has a more uniform distribution and thus in spine it is seen that there is a more predictable and linear fashion on density of bone loss. In an hip the mineral density of bone is assessed in following zones. These are, neck of femur zone, trochanter zone, intertrochanter zone, Ward's Triangle and the entire hip as whole. On assessing the wide number of zones in the entire hip, evaluation mistakes can be reduced. But, during assessment we should be vigilant as the Ward's triangle being a tiny zone,

poses a greater chance of evaluation inaccuracy or fallacy. Also must be noted that this zone sometimes be differently proposed by different maker of the machine and software. (Figure 3).

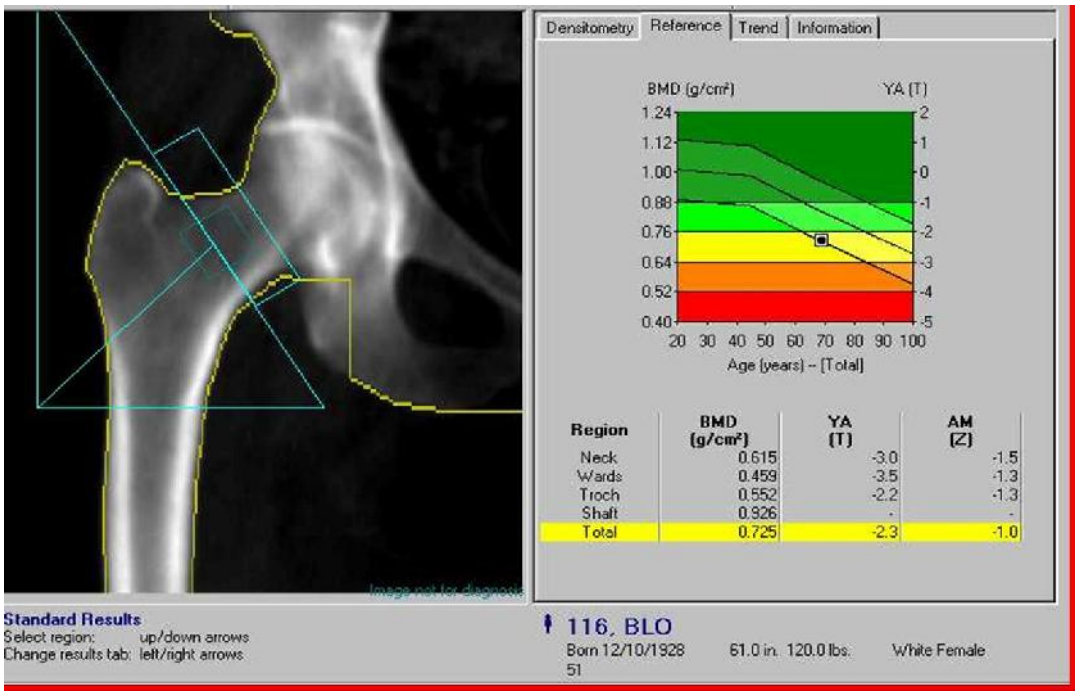


Fig 3: DEXA Scan of Hip

Mineral density of bone measurement by DEXA Scan at Spine:

The assessment of mineral density of bone by DEXA scan at spine is routinely done at lumbar vertebrae[Lumbar vertebra 1 to lumbar vertebra 4] or [lumbar vertebra 2 to lumbar vertebra 4] taken in an PA view[postero-anterior view] or Lateral projection[lateral view]. The common drawbacks with PA view is that the paraspinal ligament can be calcified or the aorta may be calcified, spinal deformities [scoliosis],osteophyte etc., may alter the results of bone mineral density measurement and may give false positive or negative readings. Also sometimes, the wedge compression fracture of the vertebral body can be identified as an area of higher osseous density. These drawbacks can be avoided with Lateral projection.

Disadvantages are also present with lateral projection. The ribcage and the pelvic bone coincide with vertebra and also there will plenty of non-osseous structure interposition. This will lead to reduction of the total number of vertebral bodies assessed, hampering the accuracy of the evaluation and therefore reduction in utilisation of it in looking or reciprocation to treatment.

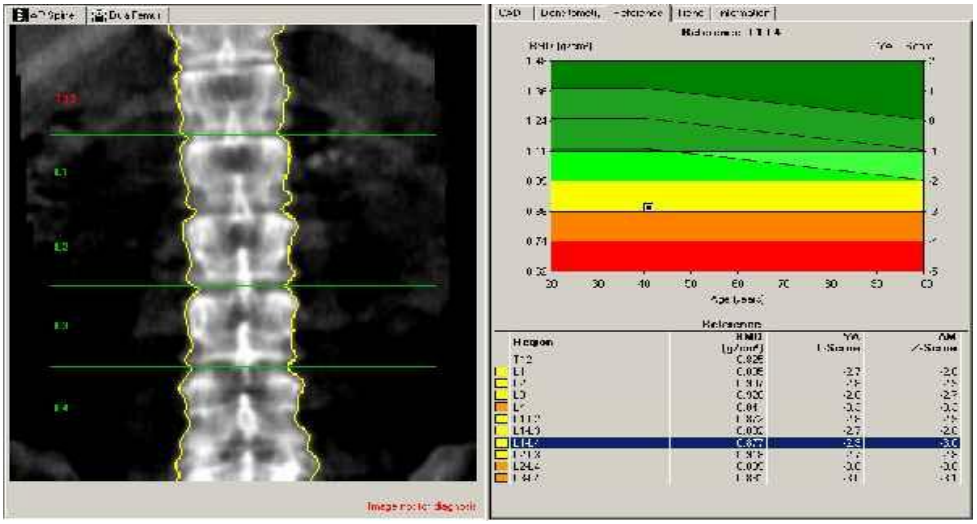


Fig 4: DEXA Scan of lumbar spine

Mineral density of bone measurement at Peripheral regions by DEXA Scan

Mineral density of bone assessment can be done at appendicular skeleton also by using the same machine used in assessing central bone mineral density i.e the normal standard DEXA scan machine. A newer advent is the introduction of numerous Peripheral consoles[Peripheral-DEXA scan machines] for assessment of mineral density of bone at peripheral sites like that at phalynx of middle digit of hand. This newer machine is FDA validated and has a significant correlation with Radio-graphic-Absorptiometry[RA].

Quantitative-Computed-Tomography[QCT][1,4]

The principle of QCT is on the property of distinctive absorption of Xray radiation by tissue with calcification. A Computerised Tomography machine is utilised and the amount of depression in the radiation traversing the structure with calcification or the osseous structure is juxtaposed with a standard reference to evaluate mineral density of the bone. In contrast to the other methods, 3D mineral density of the bone is obtained with this modality. This is a unique modality which demarcates a cancellous osseous structure and cortical osseous structure. QCT is the only technique that can distinguish between cortical and cancellous bone. The only drawback of this modality is monetary and tremendous exposure to radiation.

Ultrasonography[1,4]

It is the frequently used technique to assess the mineral density of the bone. The usual regions where it is applied are the calcaneum, wrist and the leg bones. The equipment is portable, feasible and cheaper modality when compared to other techniques. It is very well applicable for assessment in a large population[Screening].

It works on the principle that the ultrasonic wave reflection and speed depends upon the mass of the structure and depreciation of waves which is due to absorption of the waves by the material. Depreciation of waves in an osseous structure isresoluted by charting the linear correlation of the amplitude of reduction of Ultrasonic waves at different frequencies. This charting is called as Broad-band Ultrasound-Attenuation[BUA]. The depreciation of wave is the resultant of mass of osseous structure and the microscopic makeup of the osseous structure. Presently this modality is applied in screening purposes.

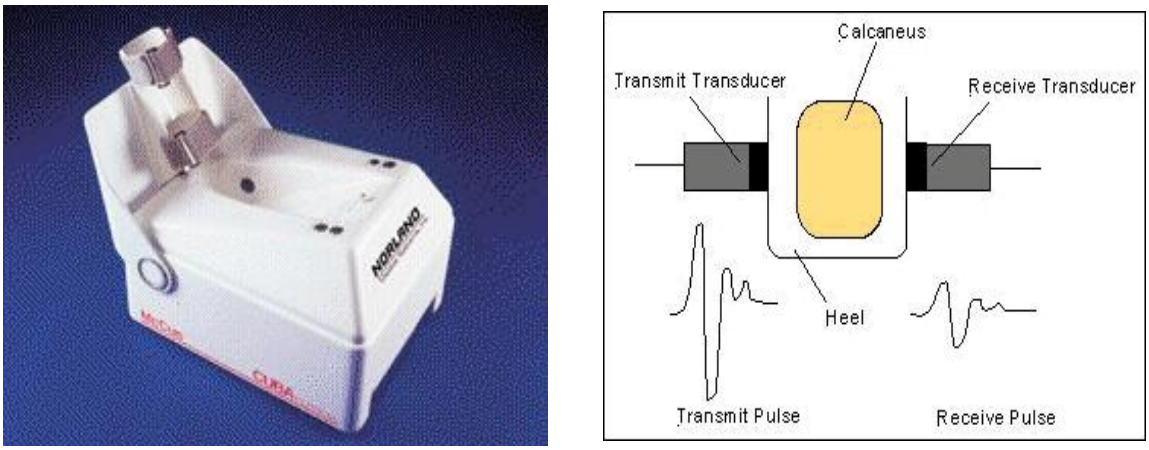


Fig 5: Calcaneal Ultrasound

Radiographic-Absorptiometry [RA][1,4]

This is a method of assessing the mineral density in the bones. It is a modality being used from almost 5 decades. With this modality evaluation of density of metacarpals and phalynx can be done. It uses simple Xray films. With the progress of technology the advanced versions use computerised software which evaluate the mineral density of the osseous structure by just loading the film or digital radiograph into the software.

METHODOLOGY

The study was done at Department of Orthopaedics, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi.

Study design:

One year Hospital based Comparative study.

Source of Data:

Data was collected from all patients above 50 years age, coming to Orthopaedics OPD or admitted under Orthopaedics department of KLE's Dr. Prabhakar Kore Hospital and MRC

Sample Size

80 Patients aged 50 year and above were selected who were willing to enroll in the study.

Sampling procedure:

Sample size was calculated by equation $4pq/d^2$ where p is prevalence of Osteoporosis in % (In a study done in Semi-urban area of Bangalore-2017,matching the demography of the present study) & was approx. 29% , q = (100-p)%, d is absolute error taken as 10%.

SELECTION CRITERIA:

Inclusion criteria-

1) All patients aged 50 years and above
2) Participants giving consent to enroll in the study

Exclusion criteria-

1. Patients on medication that interfere with calcium metabolism and homeostasis
    a. Long term steroids
    b. Anti-epileptics - Thyroxine
    c. Thyroid hormone supplements
    d. Heparin
    e. Thiazide diuretics
    f. Oestrogen
2. Patients with chronic diseases
    a. Chronic liver disease
    b. Chronic kidney diseases
    c. Chronic skin disease
    d. Rheumatoid Arthritis
    e. Malignancy
    f. Chronic bed ridden patients

Procedure:

With the clearance of Ethical and Research Committee of J.N. Medical College, Belagavi and the subjects fitting into the inclusion criteria were accordingly enrolled into the study and explained about the study and the investigations, the consent[written-informed] was obtained (Annexure–I). The consented patients were registered to the present study. Further, personal data of the participants & risk factors were evaluated through a Questionnaire .(Annexure II)

Investigation:

BMD (Bone mineral density) was evaluated by DEXA Scan of make GE Wipro and 2008 Lunar model.

DEXA Scan Evaluation technique:

A dual energy X-ray absorptiometry (DEXA) scan utilises Xray machine and a computer-software to assess the mineral density of the bone. It helps in accurate and reproducible assessment of mineral density of bone and detects osteoporosis prior to the fracture occurrence.

Pre-scan Requisites

1. Getting an written informed consent
2. Selection of the participant after fulfilling the inclusion and exclusion criteria
3. Obtaining patient data and information by the questionnaire

Instructions prior to the scan

1. Removal of clothes that have metal buttons or other metal accessories & change to a gown if necessary.
2. To remain still during the procedure.

Procedure:

The procedure is free of pain, quick and about 10 minutes. The DEXA scan equipment exposes the body to a small dose of X-ray radiation. Patient is put on to the DEXA scan equipment radiographer operates the scanning equipment.

Scan is conducted over two sites the lumbar spine followed by Bilateral hip joint. Patient is asked to flex the legs for scanning of the lumbar spine. This is done to straighten the spine. To assess the BMD of the hip joints patient is made to lie supine. The scanning equipment has a mobile X-ray tubes that passes over the patients lumbar spine & the hip joints respectively and emit Ray beams. A part of the radiations traverse through osseous skeleton and a part is absorbed by the bones – this absorption depends on the density of the bone.

A receiver measures the radiations traversing through the osseous structure and sends the information to a computer. A printed report is then obtained stating the BMD, 'T' & 'Z' scores.

The patient is then subjected to plain radiograph of either of the Hip joints with full length femur in two perpendicular plane (Antero-posterior and lateral). The calcar to canal ratio , cortical thickness index (both in AP & Lateral) and the Singh's Index is measured.

Analysis of data:

The Mineral density of bone (g/cm2) and 'Tscore' and 'Z score' is evaluated and gender.

The score is interpreted as below:

- Normal- Tscore not more than 1SD below the adult mean.
- Osteopenia- Tscore between -1.0 to -2.5
- Osteoporosis- Tscore< -2.5 +/- frailty fracture of bone.

Data is collected and recorded, the diagnosis based on the BMD score is done. BMD data obtained form the gold standard DEXA Scan is compared with the radiological indices values obtained by plain radiographs of hip joint with full length femur namely Singh Index , CTI(Ap/Lateral) , Calcar to canal ratio.(FIG.6,7,8 - source internet).

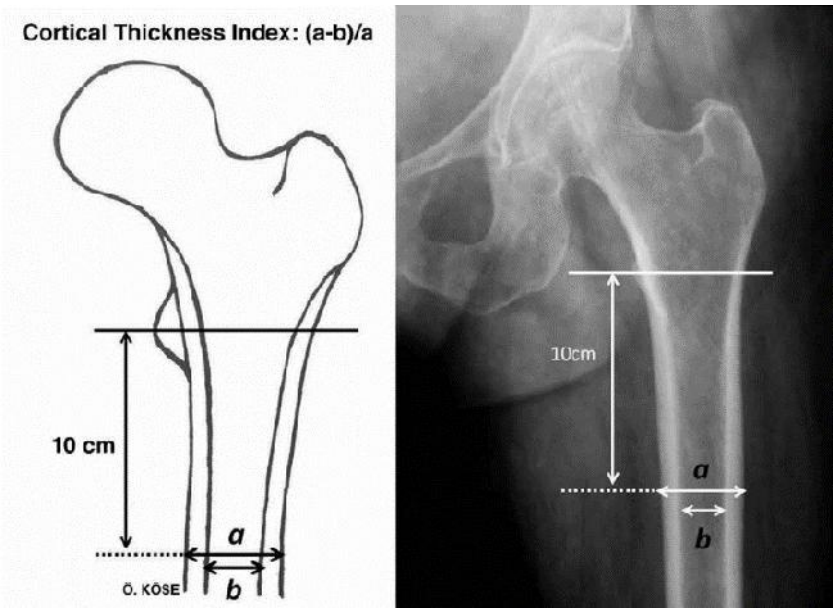


FIG.6 CTI (AP)

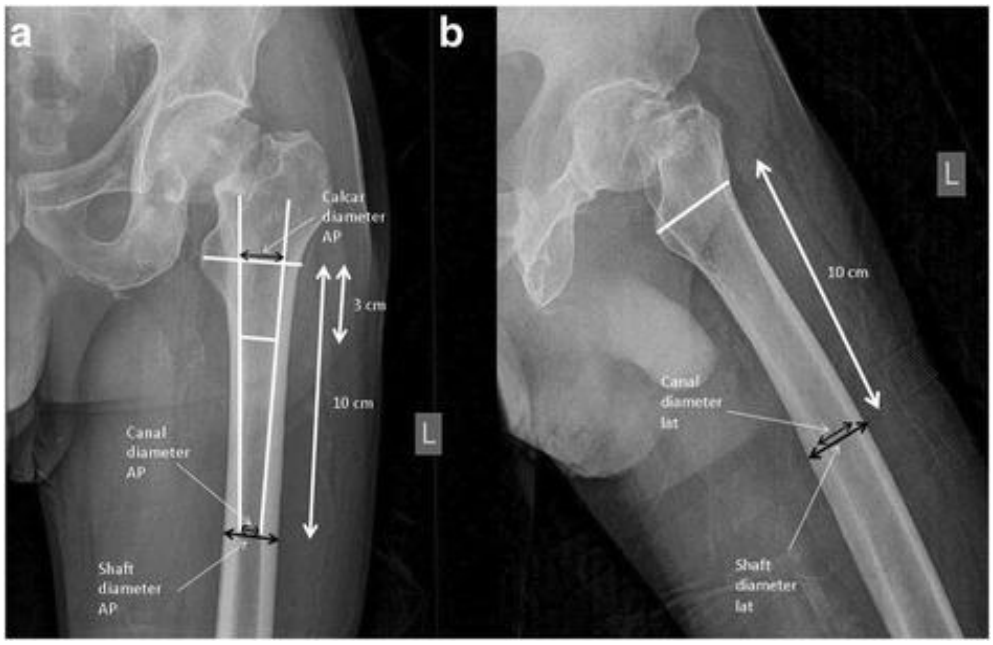


FIG.7 CTI (LATERAL)

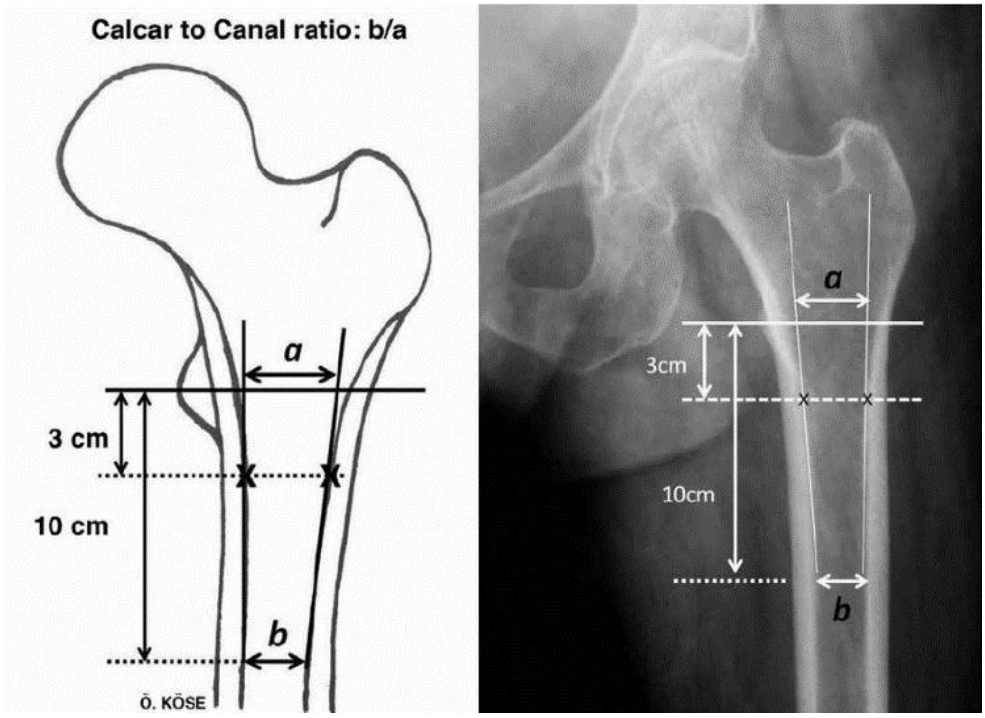


FIG.8(CALCAR CANAL RATIO)

RESULTS

A total of 80 individuals were evaluated in this study. The below are the observations made in this study-

Table no.1

SEX	NUMBER	PERCENTAGE
FEMALE	53	66.25
MALE	27	33.75
TOTAL	80	100

Out of 80 individuals examined , 66.25% were females and 33.75% were males.

Table no.2

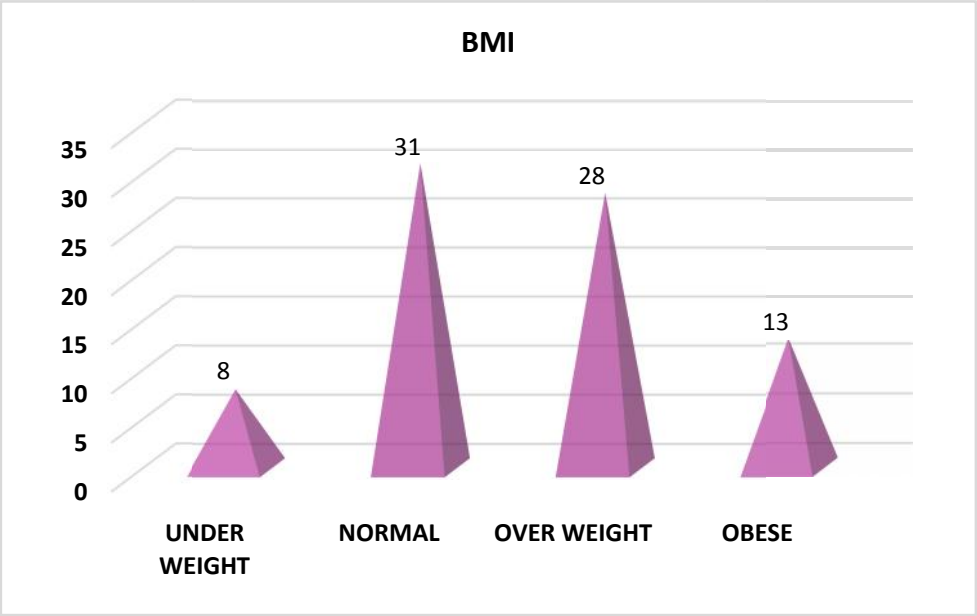
	MEAN	S.D.	MINIMUM	MAXIMUM
AGE	61.93	9.73	50	89
BMI	25.06	5.32	13.5	41

The mean age was 62 years with a minimum age of 50years and maximum of 89 years.The mean Body mass Index was 25.06kg/m^2 with lowest BMI of 13.5kg/m^2 and highest upto 41kg/m^2.

Table no. 3

BMI	NUMBER	PERCENTAGE
UNDER WEIGHT	8	10.00
NORMAL	31	38.75
OVER WEIGHT	28	35.00
OBESE	13	16.25
TOTAL	80	100.00

Chart no.1

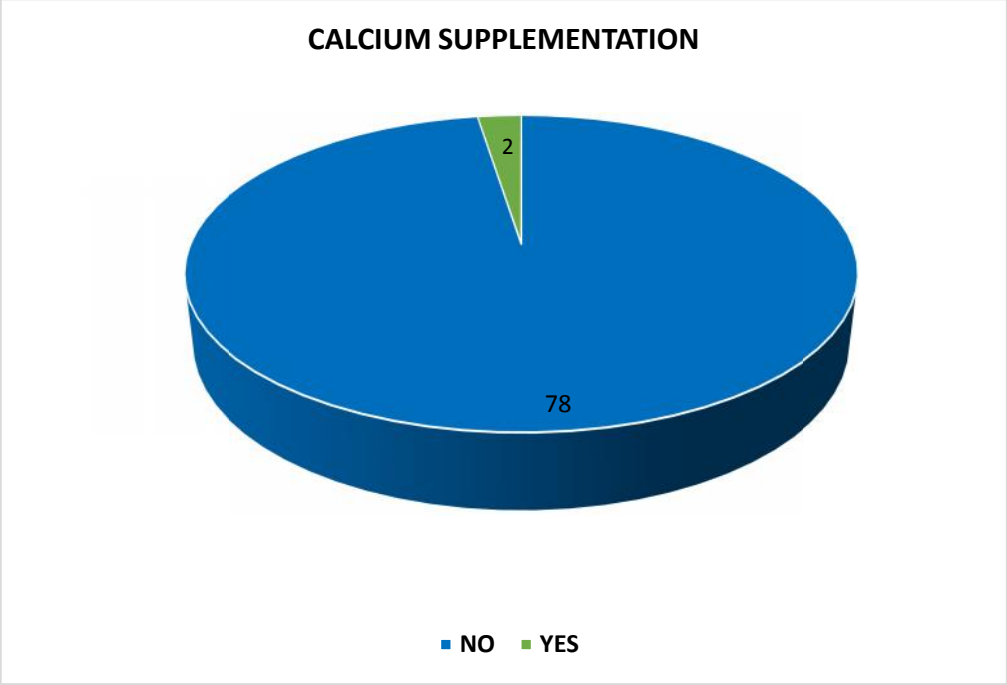


Distribution of Individuals according to BMI in kg/m^2- out of 80 individuals, 8 were underweight, 31 had normal BMI, 28 were overweight and 13 were obese.

Table no.4

CALCIUM SUPPLEMENTATION	NUMBER	PERCENTAGE
NO	78	97.50
YES	2	2.50
TOTAL	80	100.00

Chart no.2

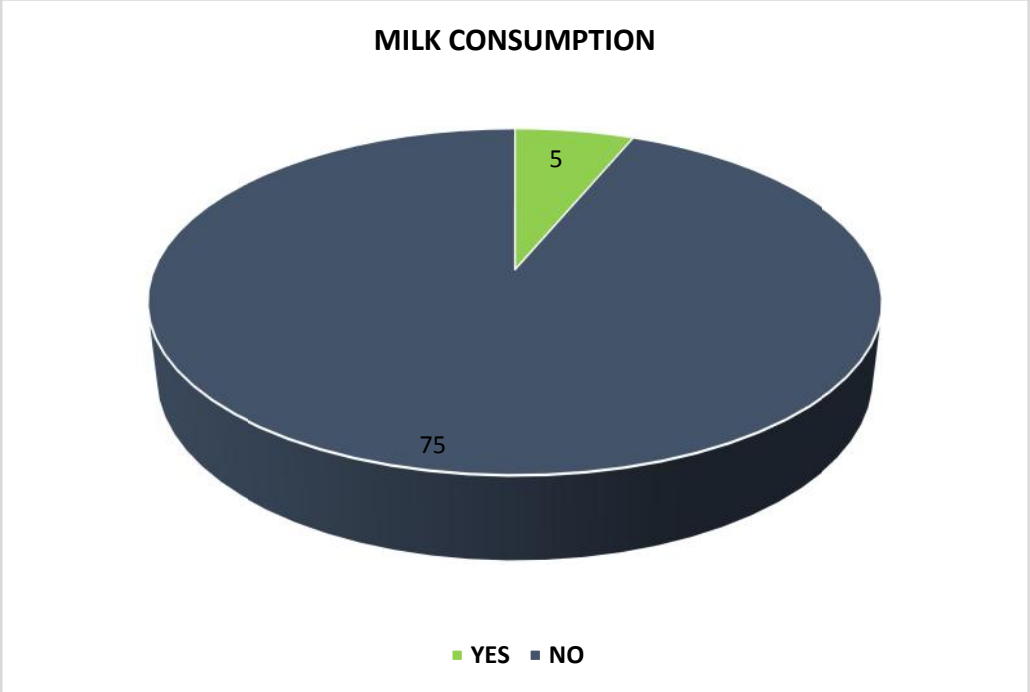


Only 2.5% individuals had the history of calcium supplementation in the form of oral tablets, i.e 2 out of 80 individuals.

Table no.5

MILK CONSUMPTION	NUMBER	PERCENTAGE
YES	5	6.25
NO	75	93.75
TOTAL	80	100.00

Chart no. 3

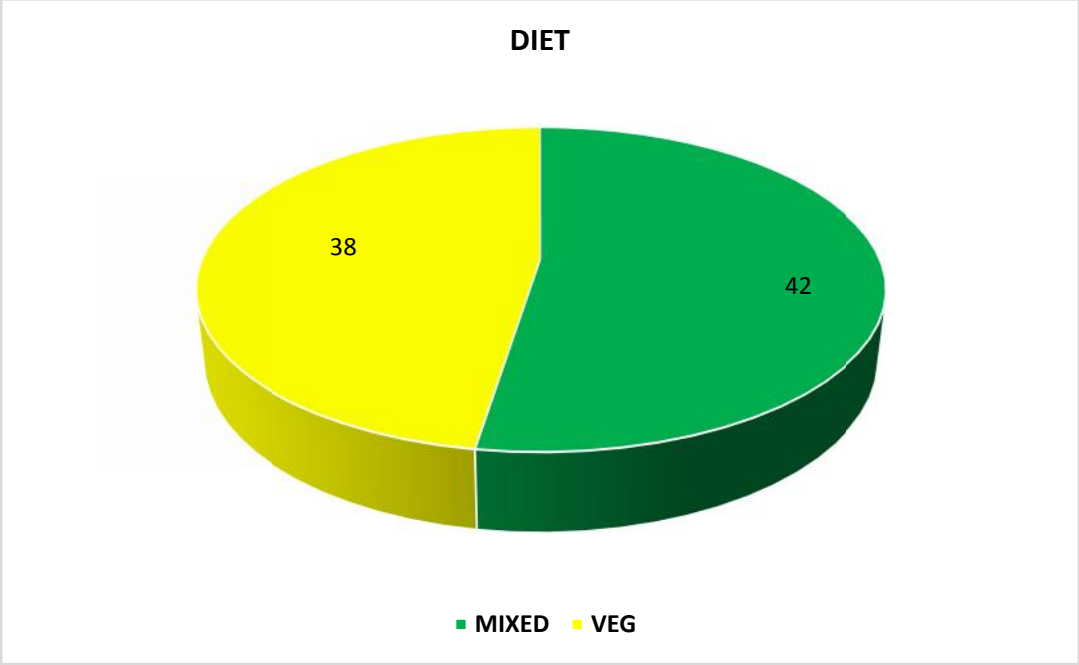


Majority of the enrolled subjects had no history of milk consumption i.e 93.75% and only 6.25% have been consuming milk.

Table no. 6

DIET	NUMBER	PERCENTAGE
MIXED	42	52.50
VEG	38	47.50
TOTAL	80	100.00

Chart no.4

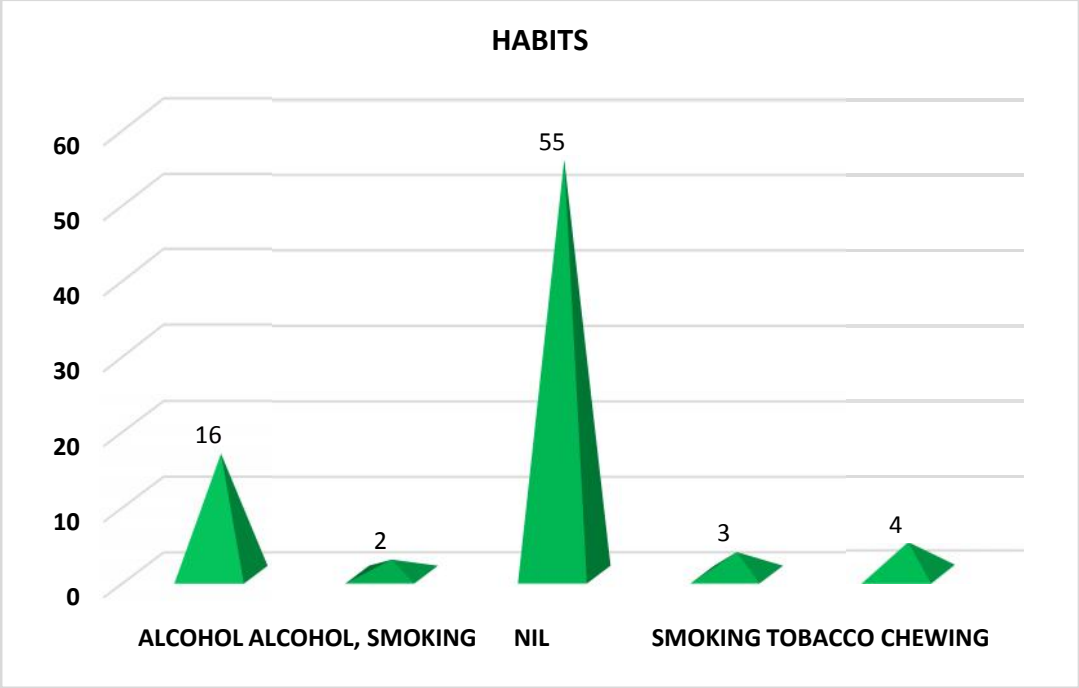


About 52.50% of the individuals were on mixed dietary habits and 42% individuals were pure vegetarians

Table no.7

HABITS	NUMBER	PERCENTAGE
ALCOHOL	16	20.00
ALCOHOL, SMOKING	2	2.50
NIL	55	68.75
SMOKING	3	3.75
TOBACCO CHEWING	4	5.00
TOTAL	80	100.00

Chart no.5

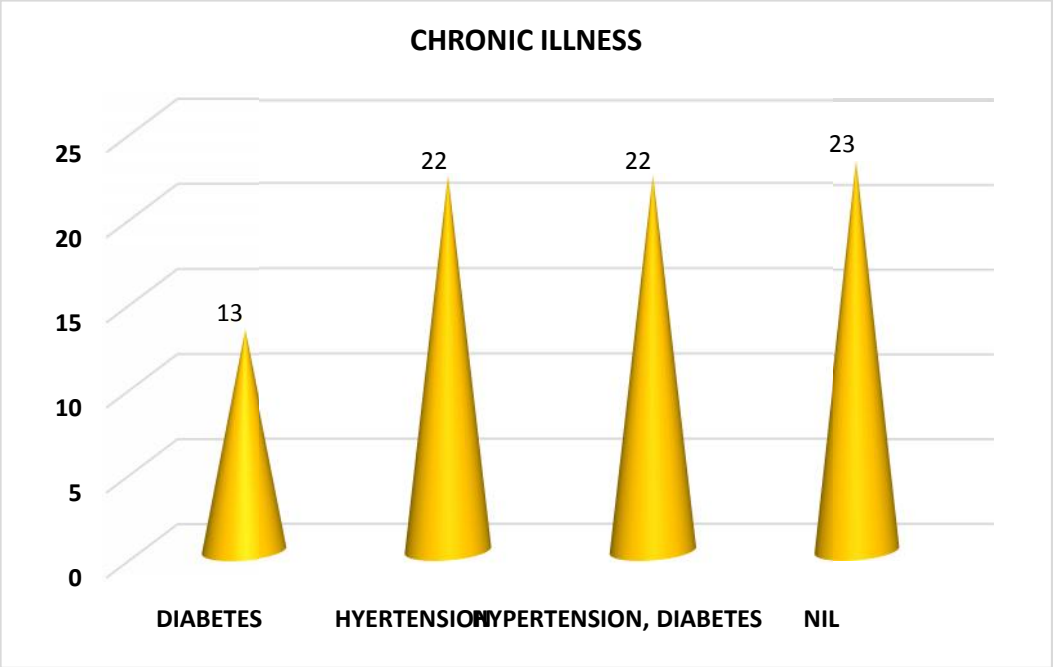


The table and graph demonstrates the no. of individuals with different habits like consumption of alcohol , smoking , tobacco chewing. All the individuals with habits were men. 55 individuals did not have history of consumption of alcohol or tobacco use. 16 people had history of alcohol consumption , 2 had history of both alcohol and smoking , 3 had history of smoking and 4 had habit of tobacco chewing.

Table no. 8

CHRONIC ILLNESS	NUMBER	PERCENTAGE
DIABETES	13	16.25
HYERTENSION	22	27.50
HYPERTENSION, DIABETES	22	27.50
NIL	23	28.75

Chart no .6

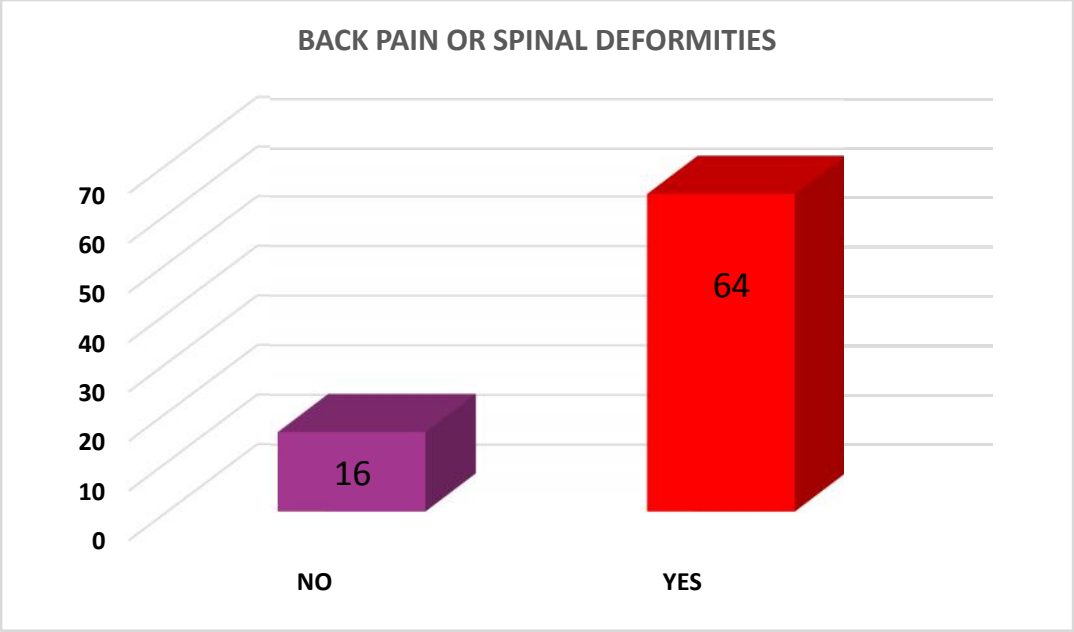


13 individuals enrolled in the study were suffering from diabetes mellitus alone, 22 were only hypertensive and 22 individuals had history of both hypertension and diabetes mellitus

Table no. 9

BACK PAIN OR SPINAL DEFORMITIES	NUMBER	PERCENTAGE
NO	16	20.00
YES	64	80.00
TOTAL	80	100.00

Chart no.7

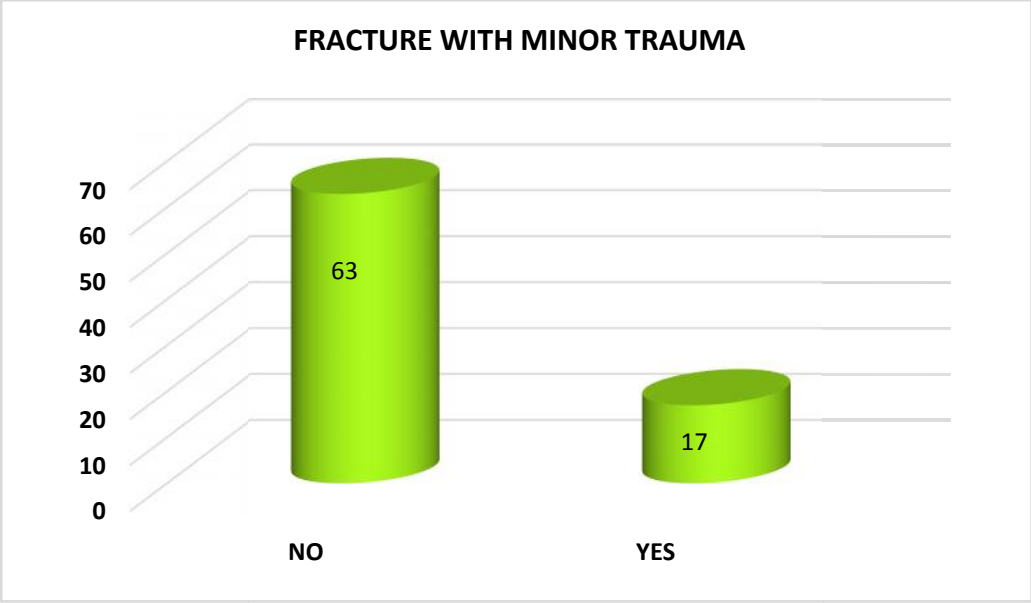


80% of the individuals enrolled in the study who underwent DEXA scan and radiographic evaluation for osteoporosis had an history of back ache for various reasons irrespective of the presence of Osteoporosis.

Table no.10

FRACTURE WITH MINOR TRAUMA	NUMBER	PERCENTAGE
NO	63	78.75
YES	17	21.25
TOTAL	80	100.00

Chart no.8



Out of 80 individuals, 17 individuals had an history of fracture with minor trauma, like femur neck fractures, Colle's fractures etc. contributing to 21.25% of the total.

Table no. 11

	MEAN	S.D.	MINIMUM	MAXIMUM
DEXA SCORE	-2.34	1.38	-6	1.8
AP(CTI)	0.49	0.08	0.38	0.69
LATERAL (CTI)	0.50	0.08	0.32	0.66
CALCAR CANAL RATIO	0.57	0.08	0.41	0.76

The mean DEXA score was -2.34 with a least score of -6 and a highest score of 1.8.The mean CTI was 0.49 and 0.50 for AP and Lateral respectively, the minimum and maximum for CTI(AP) was 0.38 and 0.69. Similarly, for CTI(lateral) was 0.32 and 0.66. The mean CCR was 0.57 with lowest of 0.41 and highest of 0.76

Table no. 12

	OSTEOPOROSIS		NO OSTEOPOROSIS	
	MEAN	**S.D.**	**MEAN**	**S.D.**
AP(CTI)	0.43	0.03	0.55	0.07
LATERAL (CTI)	0.43	0.04	0.55	0.06
CALCAR CANAL RATIO	0.50	0.04	0.62	0.06

The mean or cut off value for CTI(AP and Lateral) in Osteoporotic group was 0.43 and for Calcar canal ratio was 0.50.

Table no. 13 :Sensitivity and Specificity of Singh Index

	DEXA SCORE		
SINGH'S INDEX	**POSITIVE**	**NEGATIVE**	**TOTAL**
POSITIVE	26	6	32
NEGATIVE	10	38	48
TOTAL	36	44	80

The sensitivity for Singh Index was 72.2% and specificity was 86.36%

Table no. 14: Sensitivity and specificity of CTI (AP)

	DEXA SCORE		
AP (CTI)	**POSITIVE**	**NEGATIVE**	**TOTAL**
POSITIVE	21	15	36
NEGATIVE	0	44	44
TOTAL	21	59	80

For CTI(AP) the sensitivity was 100% with Specificity of 74.58%. The positive predictive value was 58.33% and 100% negative predictive value.

Table no. 15: Sensitivity and Specificity of CTI(Lateral)

	DEXA SCORE		
LATERAL (CTI)	**POSITIVE**	**NEGATIVE**	**TOTAL**
POSITIVE	24	12	36
NEGATIVE	0	44	44
TOTAL	24	56	80

For CTI(Lateral) the sensitivity was 100% with Specificity of 78.57%. The positive predictive value was 66.67% and 100% negative predictive value.

Table no .16 Sensitivity and Specificity of Calcar to Canal Ratio

	DEXA SCORE		
CALCAR CANAL RATIO	**POSITIVE**	**NEGATIVE**	**TOTAL**
POSITIVE	22	14	36
NEGATIVE	0	44	44
TOTAL	22	58	80

For Calcar to canal ratio the sensitivity was 100% with Specificity of 75.86%. The positive predictive value was 61.11% and 100% negative predictive value.

Table no. 17

SEX	POROSIS	%	NO POROSIS	%	TOTAL
FEMALE	28	52.83	25	47.17	53
MALE	8	29.63	19	70.37	27

p VALUE USING CHI-SQUARE TEST IS 0.0486 (S)

The sex prelidiction of Osteoporosis was tested using the Chi-Square test, and it was to be significant with a P value of 0.048, Suggesting that the females are more prone for Osteoporosis. In the present Study out of 36 Osteoporotics, 28 were women and 8 were men and the women contributing to 52.83% of Osteoporotics.

Table no. 18: Correlation of DEXA scan with the following using Spearman's Rank correlation co-efficient formula

DEXA SCORE AND	r	p VALUE	INFERENCE
SINGHS INDEX	0.6002	<0.0001	HS
AP (CTI)	0.8172	<0.0001	HS
LATERAL (CTI)	0.8243	<0.0001	HS
CCR	0.8188	<0.0001	HS

Significant correlation was found between DEXA scan and all the radiological Indices evaluated in this study.

Table no. 19: Kappa Statistics between DEXA Scores and the Following for the assessment of level of agreement:

SINGH'S INDEX

KAPPA	95% CONFIDENCE LEVELS	
0.5918	0.4503	0.7334

AP (CTI)

KAPPA	95% CONFIDENCE LEVELS	
0.6063	0.4490	0.7636

LATERAL (CTI)

KAPPA	95% CONFIDENCE LEVELS	
0.6875	0.5489	0.8261

CALCAR CANAL RATIO

KAPPA	95% CONFIDENCE LEVELS	
0.6335	0.4823	0.7847

Singh Index Shows Moderate level of agreement and the rest of the indices Show Substantial level of agreement according to Landis and Koch Kappa Statistic Criteria.

Landis and Koch Kappa Statistic Criteria.

Value of Kappa	Agreement Level
<0	No
0.01 – 0.20	Slight
0.21 – 0.40	Fair
0.41 – 0.60	Moderate
0.61 – 0.80	Substantial
0.81 – 0.99	Near Perfect

DISCUSSION

Osteoporosis is most frequently and commonly encountered in daily routine practice and is more so seen in geriatric age group. It is usually left undiagnosed or unrecognised in the peripheral setup and projects a huge burden to the community in India. It often leads to complications like hip and spinal bone fractures. Hip fractures usually have an atypical presentations like subtrochantricfractures,peri-prosthetic fractures and require surgical fixation whereas vertebral involvement present as chronic back ache, wedge compression fracture, deformity (Hunch back) etc[1] .Thus early diagnosis and treatment is of utmost importance and concern.

Assessment of mineral density of bone using a routine radiograph is been in practice since long. The advantage with this technique is, less monetary burden over the patient, less exposure to harmful radiations and easy accessibility .With the advent of DEXA scan, diagnosis of osteoporosis is precise and accurate and hence the gold standard technique .

In the year 2007,Sah et al conducted a study among the patients planned for hip replacement .They evaluated the radiological indices of the femur bone namely cortical thickness index (CTI-AP/Lat), calcar to canal ratio and Singh Index. His study showed that there is no significant correlation between Singh index and DEXA Tscore with p value-0.406 and a good correlation between cortical thickness index AP($p=0.003$ $r=0.478$) , cortical thickness index lateral ($p=0.004$,$r=0.459$) and no correlation of calcar to canal ratio ($p=0.576$) with DEXA Tscores[109]. The cut off value for CTI(AP) ,CTI(lateral) was <0.50 and <0.40 respectively.

Another similar study done by Bao NT Nguyen et al., to know the reliability of cortical thickness index of proximal end of femur as a primary parameter in assessing the mineral density of bone in osteoporosis. His results showed that there was a substantial correlation of CTI and Canal flare Index (CFI) with BMD and FRAX with individual $p<0.001$. He concluded that any value of 0.56 and 0.62 or less on CTI for men and women respectively would the taken as osteoporotic, based on his observation during the study. There was also substantial inter and intra observer agreement over CTI and CFI results[110].

Zhenyu Liu et al. evaluated Singh Index and Osteoporosis self-assessment tool in Asians to assess the risk of fracture of hip among individuals with Diabetes Mellitus. He studied two hundred sixty one females who attained menopause and eighty seven had fracture of hip. There was great difference between Singh Index among the individuals who had fracture and no fracture. He combined the area under the curve of Singh Index and Osteoporosis self-assessment tool i.e 0.795 which is much greater than individual Singh Index and Osteoporosis self-assessment tool. Therefore, concluded that combination of these two parameters can be used to assess the fracture risk in T2DM individuals[111].

Deeptiman James et al. studied plain radiographs of 285 individuals including both men and women in rural central of India at CMC Vellore , eighty four percent of the radiographs of the individuals were tagged 3 or below according to Singh grading, and concluded that the using Singh Index to diagnose osteoporosis in a rural setup is both cost effective and efficient[112].

Another study done by Hitesh Vohra et al. to check for accuracy of Singh Index with respect to DEXA scan, a total of 30 patients were evaluated and found that

there was a fair level of agreement(kappa=0.348) and no good correlation between the Singh Index and concluded that it cannot be a good index for assessing and recognising Osteoporosis[113].

In a study done by Sandeep Krishna A to assess whether the use of Singh with Digital Radiogram is useful in diagnosing porosis of bone, it showed that there was good correlation of DEXA scan and Singh Index on plain radiogram taken with digital radiometry with accuracy of seventy two percent , sensitivity of 68.42percent and specificity of 83.33percent. Thus concluded that the Singh Index is useful in screening of osteoporosis when radiographs taken with digital Xray[114].

In this study, our primary aim was to evaluate the reliability of radiological indices namely Singh Index, cortical thickness index (CTI) AP and Lateral,Calcar to canal ratio in comparison with the benchmark standard Dual –Energy-Xray – Absorptiometry in the diagnosis of Osteoporosis. 80 individuals aged 50years and more were examined , DEXA scan was done and the T-score was noted, they also underwent plain radiograph of the hip joint with full length femur in both Anterior-posterior and lateral views. The Singh Index, CTI(AP/lateral) and calcar canal ratio was deduced and noted. These radiological indices were compared with the DEXA T-scores. Also basic information of the patient like age , BMI, complaints , habits , any chronic diseases , calcium supplementation , milk consumption , any fractures due to minor trauma etc was collected through a proforma which are mentioned in the results Out of 80 patients , 66.25 % were females and 33.75% were males with the mean age was 62 years. 52.83% females and 29.63% males were osteoporotic. About 80percent of the patients had history of backache, only a negligible percent of patient had

history of calcium supplementation and milk consumption i.e 2.50% and 6.25 % respectively. Around 21.25% patient had an history of fracture with minor trauma.

The CTI(AP) cut off value for osteoporotic was 0.43, sensitivity for CTI(AP) was 100% , specificity was 74.58%. The positive predictive was 58.33% and negative predictive value was 100%. There correlation with DEXA scan T-score and the CTI(AP) was measured using the spearmen correlation co-efficient (*r=0.8172*,p<0.0001) showed a substantial correlation of CTI(AP) with DEXA scan and also had a significant level of agreement (kappa=0.6063). Similarly , the mean CTI(lateral) cut off value for osteoporosis was 0.43 , sensitivity was 100% , specificity was 78.57 %.The positive predictive value was 66.67% and negative predictive value was 100%.CTI(lateral) also had a substantial level of agreement (kappa=0.6875). There was a strong correlation between CTI(lateral) and DEXA T score with Spearmen co-efficient(*r=0.8243* p<0.0001).

The cut off value for calcar to canal ratio for diagnosing osteoporosis was 0.50, sensitivity was 100%, specificity was 75.86%, positive predictive value was 61.11% and negative predictive value was 100%. Here also there was a significant correlation with DEXA T- score on evaluation with Spearman co-efficient(*r=0.8188,* p<0.0001) and a significant level of agreement (kappa=0.6335).

In contrast, to study done by Sah et al. with cut off value of CTI(AP) was 0.50, CTI(Lateral) was 0.40[109] , and study done by Andy K.S.Yeo et al the CTI(AP) and CTI(lateral) cut off was 0.40[108] , Our study showed cut off value of 0.43 for both CTI(AP) and CTI(lateral). This might be due to the different characteristics of the patient as the other studies were done in western countries and also the mean age in our study was comparatively less than in others studies i.e 61 years whereas in other

studies it was 67 years and 79 years respectively. The patients in these studies might have an established bone mineral loss and osteoporosis, also the patient had hip fractures and this fracture might have altered the density of the bone at the femur neck.

In the studies mentioned above it was concluded that the calcar to canal ratio had no significant correlation with the DEXA T- scores , but the present study showed a significant correlation with a cut off value of 0.50 and a specificity of 75.86 % and spearman co-efficent of $r=0.8188$, $p<0.0001$. This might be due the difference in the long bone morphometric, bone mineral density, genetic factors etc. of the western individuals to that of the Indian population.

There has always been a great argument and dispute regarding the reliability of use of Singh Index in establishing Osteoporosis. Sah et al in his concluded that there is no significant correlation between Singh Index and DEXA scan[109]. Similarly, Hitesh vora et al study revealed that there was no significant correlation and had a fair level of agreement with kappa=0.348 and concluded that the Singh Index is not reliable[113].

In contrast, Study done by Deeptiman James et al , suggested that Singh Index is reliable and can be used for screening of Osteoporosis[112] , also in a study done by Sandeep Krishna A. et al assessed the Singh Index by Plain radiogram using digital Xray system. This study revealed a significant correlation with DEXA Scan with Sensitivity of 68.42 % and specificity of 83.33%[114]. This significance may due to clearer Xray films due to Digital radiography compared to conventional radiographs in which the trabecular pattern may be masked due to fat overlap and also single observer leading to bias.

According to the present study, the Singh Index showed significant correlation with DEXA T scores with sensitivity of 72.22% and specificity of 86.36%. In this study also, digital Xray was used and a single Observer with moderate level of agreement (kappa=0.591).

It was also seen that the patients who had different T- scores had same Singh grade. In 1984 , study done by Lips et al. showed low reproducibility of the Singh Index[115] , also V.C.M Koot et al study showed that there was a significant intraobserver acceptance i.e kappa between 0.63 to 0.88 but poor interobserver acceptance and there low reproducibility and reliability[104]. Therefore, Singh Index is not reliable in diagnosis of Osteoporosis.

CONCLUSION

In this comparative study, 80 individual were evaluated for assessing the Reliability of the radiological indices in comparison with standard Dual- Energy Xray Absorptiometry in the diagnosis of Osteoporosis.

The overall load of Osteoporosis was 45%, with majority in females contributing to about 52.83%. The mean age among both the sexes was 62 years and the age range from 50years to 89 years. The average BMI was 25.06 kg/m^2 and ranged between a minimum of 13.5kg/m^2 to a maximum of 41kg/m^2. Only a negligible percentage of 2.5% and 5 % had an history of calcium supplementation and milk consumption respectively.

About 22.5% had an history of alcohol consumption and a total of approximately 11% had an history of tobacco abuse in any form either smoking or chewing. 38 % individuals had vegetarian food habit and 42% had mixed food habits. 16.25 % and 27.5% were suffering from diabetes and hypertension respectively and 27.5% patients had history of both diabetes and hypertension.

Majority had complaint of backache for several reasons irrespective of the presence of osteoporosis, contributing to about 80% and around 21.25% individuals had a history of fracture due to minor trauma.

The CTI(AP/Lateral) along with calcar canal ratio had a significant correlation with the DEXA T- score and had a substantial level of agreement with kappa value between 0.6063 to 0.6875. The cut off value for diagnosis of osteoporosis for CTI- Ap and Lateral both was 0.43 and for calcar to canal ratio was 0.50. With consideration of higher specificity, sensitivity, positive predictive value and substantial level of

agreement on kappa score CTI(Lateral) is more specific and reliable in the diagnosis of osteoporosis.

The Singh Index though had an good sensitivity and specificity, due to limitations of poor reproducibility, technical difficulties and observer bias, it is not reliable in the diagnosis of Osteoporosis.

Overall, Radiological indices except Singh's index are both Reliable and cost effective in the diagnosis of Osteoporosis.

SUMMARY

- The study was done to assess the Reliability of Radiological Indices in comparison with Dual Energy Xray Absorptiometry in the diagnosis of Osteoporosis –A one year Hospital based comparative study
- Objective of the Study :

  1) To assess the Reliability of Radiological Indices in comparison with Dual Energy Xray Absorptiometry in the diagnosis of Osteoporosis.

  2) To assess the Cost effectiveness of the Radiological Indices over DEXA scan.

- Through a questionnaire patient demographic details and personal data was collected and the patient were taken in to study who met the inclusion and exclusion criteria.
- The patients who underwent DEXA Scan and T- scores were noted. The patients were further subjected to plain radiographs Anterior-posterior and lateral Views. Radiological Indices namely, Singh Index, CTI(AP/Lateral), Calcar to Canal ratio were calculated and noted.
- The results were evaluated by statistical analysis using SPSS software and tabulated.
- A cut off of 0.43 for both CTI (AP & Lateral) and 0.50 for CCR was deduced. There was a Significant correlation seen with DEXA scores using Spearman's Rank Co-efficient($p<0.0001$) and a Substantial level of agreement using Kappa statistics. With greater Sensitivity and specificity,positive predictive value CTI(lateral) is more reliable compared to other indices in this study.
- Though there was a significant correlation of Singh Index with DEXAScores, due to its limitations of reproducibility, observer bias, technical limitations with the

Radiography, and application to a larger population, it is concluded that Singh Index is not reliable in diagnosis of Osteoporosis.

- Radiological indices are both Reliable and cost effective in the diagnosis of Osteoporosis.

LIMITATIONS OF THE STUDY

- The study was conducted by a single investigator, observer bias may be a drawback.
- Out of 80 subjects, 36 individuals were osteoporotic. If more number of osteoporotic individual's radiological indices were assessed, then the results would have been more statistically accurate and refined.
- The present study is a single centric study with a sample size of 80. Thus, we suggest multicentric, large sample size studies to prove similar hypothesis.

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INFORMED CONSENT

"RELIABILITY OF RADIOLOGICAL INDICES IN COMPARISON WITH DUAL ENERGY X-RAY ABSORPTIOMETRY IN DIAGNOSIS OF OSTEOPOROSIS –A ONE YEAR HOSPITAL BASED COMPARATIVE STUDY"

PRINCIPAL INVESTIGATOR: Dr. _____

INTRODUCTION AND PURPOSE: The present study is conducted among patients who are presenting to orthopaedics OPD/IPD of KLE Dr. PRABHAKAR KORE HOSPITAL AND MRC, BELAGAVI aged above 50 years to assess the **RELIABILITY OF RADIOLOGICAL INDICES IN COMPARISON WITH DUAL ENERGY X-RAY ABSORPTIOMETRY IN DIAGNOSIS OF OSTEOPOROSIS**. You are requested to participate in the study and your participation is completely voluntary.

PROCEDURE: If you agree to participate in this study, the relevant data will be collected as per the proforma and the final diagnosis will be confirmed.After getting inducted in the study, you will be evaluated, complete detailed history will be taken and thereafter x-ray of the FEMUR, followed by DEXA scan will be done on opd or ipd basis. The test is painless and can be performed within 5-15 minutes. The procedure is done only once.

BENEFITS:

1) You will not be eligible for any kind of monetary benefits or free services by virtue of participation in the study.
2) As an ailment in early diagnosis and treatment initiation in osteoporosis.

RISKS:

NO RISKS ASSOCIATED WITH THE STUDY

WITHDRAWING / REMOVAL FROM STUDY:

You can withdraw from the study anytime you want to.

PRIVACY AND CONFIDENTIALITY:

All information about the subject during the course of the study will be kept confidential to the extent permitted by law.

COSTS:

X-RAY (PELVIS) – RS 300

DEXA SCAN – RS 1200

AUTHORISATION TO PUBLISH THE RESULTS:

The researcher may use the information gathered from this study for presentation in scientific meetings. However your identity will not be revealed.

QUERIES:

If you have any queries regarding study, you can contact Dr._____ without any hesitation on -_____ and the guide Dr._____ If you have any questions about rights of a research participant, you can contact:Dr.RoopaBellad, Professor of Dept. of Paediatrics and Chairman Ethical Committee on Human subjects, J .N MEDICAL COLLEGE, BELAGAVI.

CONSENT SUMMARY:

I have been explained all the contents of this consent form in my vernacular language and having understood and clarified all my queries about the study to best of my knowledge, i hereby give voluntary consent for participation in the study. I do sign the informed consent form in front of an eyewitness whom i recognize.

NAME AND SIGNATURE / LEFT THUMB IMPRESSION OF THE PARTICIPANT:

NAME AND SIGNATURE OF THE INTERVIEWER:

NAME AND SIGNATURE / LEFT THUMB IMPRESSION OF EYEWITNESS:

SIGNATURE OF THE GUIDE

DATE:

ANNEXURE II.ETHICAL CLEARANCE.

K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 - 2470759

Ref: MDC/DOME/ 65 **Date: 22/11/2017**

To,

PG student in Orthopaedics.
J.N.Medical College.
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"RELIABILITY OF RADIOLOGICAL INDICES IN COMPARISON WITH DUAL ENERGY X –RAY ABSORBTIOMETRY IN DIAGNOSIS OF OSTEOPOROSIS – A ONE YEAR HOSPITAL BASED COMPARATIVE STUDY"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman.
JNMC Institutional Ethics Committee
on Human Subjects Research.
J.N.Medical College, Belagavi.

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PROFORMA

"RELIABILITY OF RADIOLOGICAL INDICES IN COMPARISON WITH DUAL ENERGY X-RAY ABSORPTIOMETRY IN DIAGNOSIS OF OSTEOPOROSIS –A ONE YEAR HOSPITAL BASED COMPARATIVE STUDY"

PATIENT ID -

NAME: **AGE:**

ADDRESS:

OCCUPATION:

WEIGHT: **HEIGHT:** **BMI:** **KG/mSq**

CHIEF COMPLAINTS:

1)

2)

1) **ON ANY MEDICATIONS:** **[ ] YES** **[ ] NO**

SPECIFY IF YES_____

2) **ANY CALCIUM / VITAMIN D SUPPLEMENTATION : [ ] YES[ ] NO**

3) **HABITS : [ ] ALCOHOL[ ] SMOKING [ ] TOBACCO [ ] OTHERS**

SPECIFY _____

4) ANY PREVIOUS HOSPITALISATION- [ ] YES [ ] NO

SPECIFY IF YES: _____

5) ANY CHRONIC DISEASES:

[ ] DIABETES MELLITUS

[ ] HYPERTENSION

[ ] EPILEPSY

[ ] CHRONIC KIDNEY DISEASE ON DIALYSIS

[ ] MALIGNANCY

[ ] RHEUMATOID ARTHRITIS

[ ] PSORIASIS

6) DIET- **[ ] VEG [ ] MIXED**

7) MILK CONSUMPTION **[ ] YES [ ] NO**

IF YES HOW MUCH_____

8) BACK PAIN OR ANY SPINAL DEFORMITIES [ ] YES [ ] NO

9) H/O OF ANY FRACTURES DUE TO MINOR TRAUMA [ ] YES [ ] NO

SL N O.	DEXA SCORE	SINGH INDEX GRADE	A-P (CTI)	LATERAL (CTI)	CALCAR CANAL RATIO
1					

ANNEXURE -IV PHOTOGRAPHS

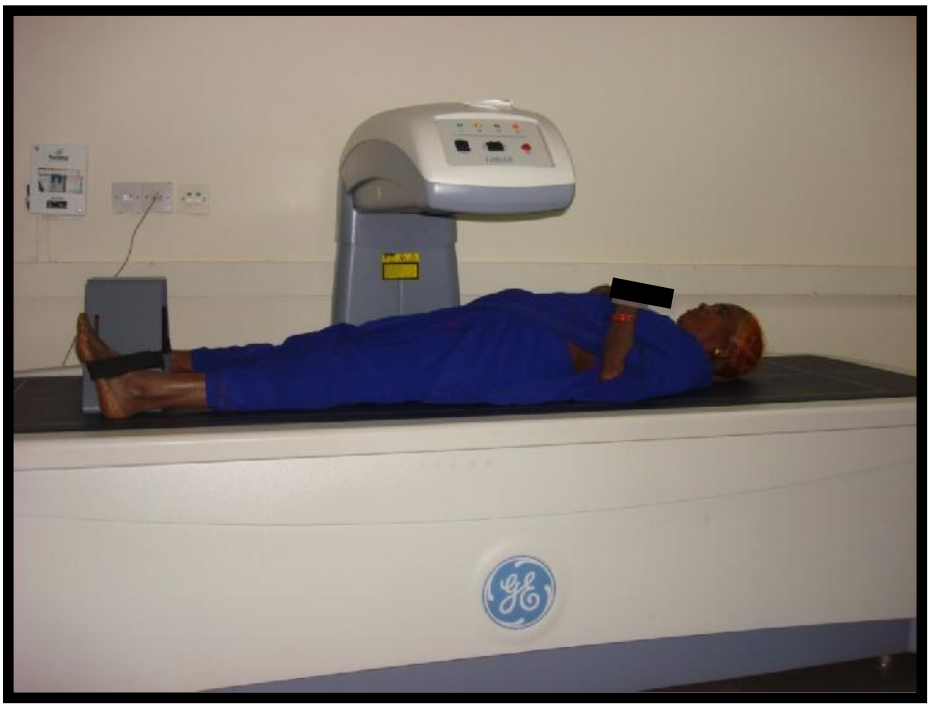


Fig 9 :DEXA SCAN OF DUAL HIP

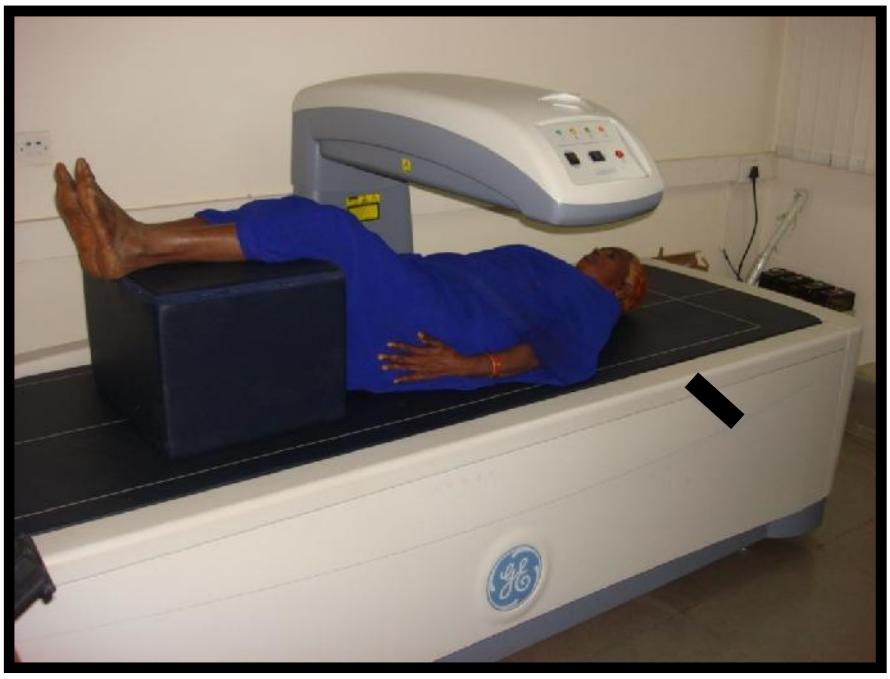
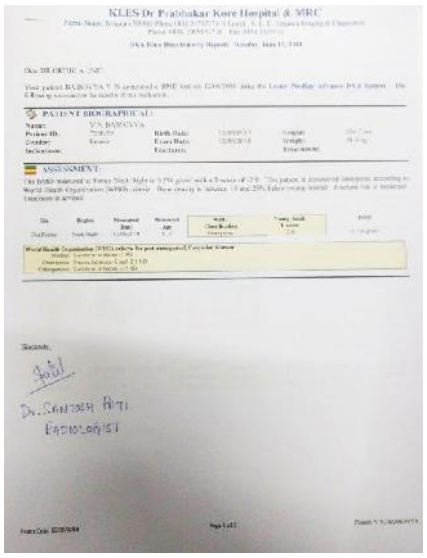


Fig 10: DEXA SCAN OF LUMBAR SPINE



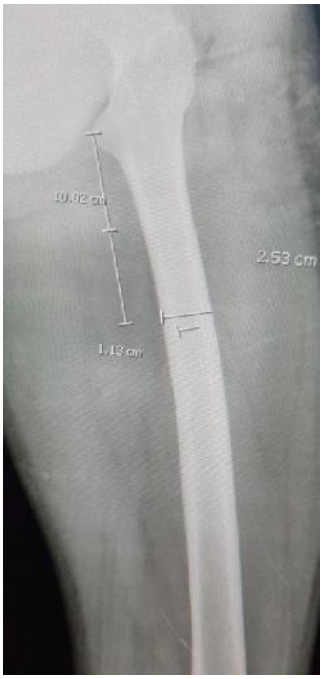


Fig 11: MEASUREMENT OF RADIOLOGICAL INDICES – SL NO.13 IN MASTER CHART -SINGH'S INDEX= 4 , DEXA SCORE= -2 , CTI(AP)=0.6 , CTI(LAT)=0.55 ,CCR=0.66

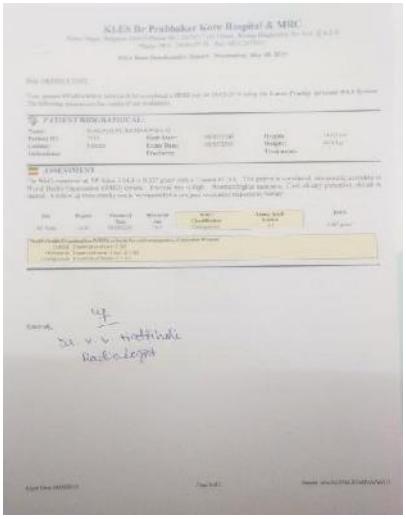


Fig12:MEASUREMENT OF RADIOLOGICAL INDICES – SL NO.29 IN MASTER CHART -SINGH'S INDEX= 3, DEXA SCORE= -3.1, CTI(AP)=0.44 , CTI(LAT)=0.41 ,CCR=0.49