USOFRA study using QUS Ultrasound of the heel bone to detect osteoporosis demonstrating height loss as a vital risk factor in women

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Abstract:

Background: Osteoporosis, is a silent progressive disease associated with low bone density and resultant deterioration of bone micro architecture and fragility fractures.

Unfortunately, the Dexa-Scan is not widely available, it is expensive and involves exposure to some amount of radiation.

India is a developing country with limited health resources and economic restrictions. Evolving cost- effective methods to detect osteoporosis with possibilities of widespread usage are desirable.

Material & Methods: Detailed clinical data, height, weight and T- score measurements from QUS heel studies of 1843 patients (including 1225 females & 518 male) were obtained from the USOFRA (Uma Sanjeevani Osteoporosis screening and Fracture Risk Assessment) study from 2008 till date.

Observations: The study demonstrates an increasing incidence of severe height loss with advancing age & correspondingly higher incidence of fragility fractures.

403 Women with Mild Height Loss (<1") having no Fragility fractures had high T- scores.

105 Women with Severe Height Loss (>1") with Fragility fractures had the low T-scores especially in the younger women aged 40 – 60.

The heavier women aged 40 – 60 years, who suffered mild height loss, had much stronger bones evident by their highest T-scores, than the women who were light and had severe height loss, who had the lowest T-scores.

Discussion: It was found that additional clinical risk factor 'Severe Height Loss (>1), which when coupled with low body weight <65 kg, and QUS heel T-score< -1.0' showed greater risk of fragility fractures.

Conclusions: The study demonstrated that Height Loss more than 1" and low body weight are significant risk factors which together with a low T-score, help in the detection of osteoporosis.

Severe Height Loss (>1") obtained by deducting present height measurement from self-reported height known from youth (age 20-25), is a valuable clinical risk factor for osteoporosis. It can be used in women aged 40 years and above as a screening tool for early detection of osteoporosis.

Keywords: Post-menopausal Osteoporosis; Osteopenia; QUS Heel; T-score; BMD; Height Loss; Clinical Risk Factors; Fragility Fracture.

Introduction

Osteoporosis, is a silent progressive disease resulting in low bone density and deterioration of microarchitecture of the bone resulting in fragility fractures[(1)]. It has emerged as a major health concern and now poses a new challenge in the care of the geriatric population[(2)]. If detected in time, fragility fractures associated with low bone density, can be prevented.

Post-menopausal osteoporosis, in contrast with Senile Osteoporosis, occurs in young women in the decades following menopause. Women with an early onset of menopause are therefore at high risk of osteoporosis at a much younger age.

The occurrence of fragility fractures and in particular hip fracture is expected to increase to four times the present incidence by 2050.[(3,4)]

The Gold standard test for detecting osteoporosis with reasonable accuracy is the DEXA-SCAN (Dual Energy X-ray Absorptiometry) of the Lumbar Spine, Hip & Distal Forearm[(5)].

Unfortunately, the DEXA-SCAN is not widely available, it is expensive and involves exposure to some amount of radiation.

In a developing country like India with limited health resources and economic restrictions, evolving cost effective methods to detect osteoporosis with possibilities of widespread usage are desirable[(6,7)].

The USOFRA (Uma Sanjeevani Osteoporosis screening and Fracture Risk Assessment) Study utilized detection methods that are cost effective, radiation free, with an ease of portability of the equipment used[(8,9,10,11,12,13,14)].

Utilizing the Quantitative Heel Ultrasound technique, we have combined the T score obtained with a Clinical Risk Factor Assessment.

Elsewhere investigators have also used clinical risk factors along with T scores obtained by quantitative heel ultrasound[(15,16)].

In this study, significant Height Loss (more than 1"), apart from Low Body weight (<65 kg) showed a strong correlation with the presence of low T-scores signaling osteopenia & osteoporosis. Regular exercise

in the post & peri-menopausal (40 – 65) & high calcium diet also showed mild association with stronger bones.

The USOFRA study being conducted at Uma Sanjeevani Hospitals, Gurgaon, is also engaged in expanding the assessment to show that the women at high risk and not taking precaution are also the ones who have a significant risk of fragility fractures over the years. We are in the process of devising a simplified scoring system to decide which patients need further investigation and more stringent management to prevent fractures.

Materials and Methods

In this study, data has been obtained from the ongoing USOFRA study from 2008 till date (Table 1).

The aim was to compare the predictive value of the QUS Heel device in the course of visits involving 1843 patients, including 1225 females & 518 males.

The study includes Indian women & men of all age groups visiting our two Centres in Gurgaon.

The data was obtained from a detailed proforma filled in by the patients with the help of our nurses & volunteers. The clinical data included measurements and relevant history was checked & verified by our team of investigators, compiled on a chart, part of which is produced here (Table 1 & 2).

Exclusion criteria: Women with postural variations, muscle group weakness, severe back disease, kyphosis and other spinal deformities, and wheel chair bound/bedridden were not included in this study.

Comprehensive data obtained included personal information as follows:

- Name,
- Age,
- Sex,
- Date of birth,
- Height (as known from youth, measured in feet & inches),
- Weight in youth (whether, normal, underweight or overweight)
- Telephone no.,
- Address

Clinical data i.e. measurements

- Present height,
- Present weight.

Relevant history

- Family history of stoop/fracture hip/other fracture
- Menopause age
- Surgical menopause,
- Dietary calcium intake from non-vegetarian food, milk & milk products and green leafy vegetables
- Details of exercise
- Diseases including thyroid, RA, diabetes
- Medication
- Steroid intake
- Smoking
- Alcohol
- Details of fractures if any
- Frequent falls
- Chair test
- Details of latest relevant laboratory reports (Serum Ca, Ph, alkaline phosphatase, 25.OH.vitD3, PTH, TSH, Creatinine or Creatinine clearance) are also recorded.

Readings are taken by the QUS Heel test.

The Quantitative Ultrasound Heel test is performed by a trained expert technician regularly visiting our centre and attached to the ultrasound machine supplier. The machine used by us is the CM 200 Furon.

A few checks are performed during and before usage to standardize the readings and check their accuracy.

Noting's are made of the T-score, Z-score, BUA and SOS readings and corresponding Stiffness index readings for each patient's right heel.

Further details of previous bone densitometry checks including Dexa scans, heel or other bone density test reports and treatment details, including calcium, vitamin D, and osteoporosis therapy details are recorded.

Height loss was determined and used as one of the criteria in this study. It was calculated by subtracting present height in cm from earlier self-reported height known from the early 20's.

Observations

Table 1

No. of women	Age	Height (in youth)	Present Ht (cm)	Wt(kg)	BMI	T-score QUS heel	Ht loss >1"/<1"/<0.5"	Family History of Osteoporosis	Parental other fracture	Parental Hip fracture	Good/Poor Diet Calcium
136	<40	159.2	158.2	62.8	25.0	-0.2	17/23/73	28	10	4	54/82
194	40-50	158.8	157.6	67.3	27.1	-0.7	37/35/101	83	36	14	88/106
298	50-60	157.7	155.5	66.9	27.7	-1.0	76/45/117	92	36	23	153/145
352	60-70	157.5	154.0	63.8	27.0	-1.5	148/65/66	129	38	49	188/164
156	70-80	155.7	151.9	62.5	27.1	-1.9	79/15/22	57	12	19	67/89

No. of women	Age	Smoking	Post Menopausal	Diseases	Medications	Steroids	Good/Poor Exerciser	Frequent Falls	Fragility #s/High Vel. #s	Positive Chair Test	
136	<40	3	2	44	0	8	25/111	4	10/16	0	
194	40-50	6	59	90	1/193	15	89/105	8/193	11/37	3/159	
298	50-60	1	273	156	10/297	23	131/167	18/296	47/49	7/232	
352	60-70	5	348	200	10/348	35/351	173/179	29	83/45/222	12/296	
156	70-80	3	156	99/154	19/154	4/154	73/83	25/153	48/27/79	16/139	

Table 2: The Bar Diagram (A) (below) shows graphic representation of data from Table 2. Increasing incidence of severe height loss (>1") with advancing age is demonstrated in this study of 1136 women

No. of women	Age	Height (in youth)	Present Ht (cm)	Wt(kg)	BMI	T-score QUS heel	Ht loss >1"/<1"/<0.5"	Total no. measured for height loss	>1"	<1"	<0.5"
136	<40	159.2	158.2	62.8	25.0	-0.2	17/23/73	113	15.0%	20.4%	64.6%
194	40-50	158.8	157.6	67.3	27.1	-0.7	37/35/101	173	21.4%	20.2%	58.4%
298	50-60	157.7	155.5	66.9	27.7	-1.0	76/45/117	238	31.9%	18.9%	49.2%
352	60-70	157.5	154.0	63.8	27.0	-1.5	148/65/66	279	53.0%	23.3%	23.7%
156	70-80	155.7	151.9	62.5	27.1	-1.9	79/15/22	116	68.1%	12.9%	19.0%

(A)

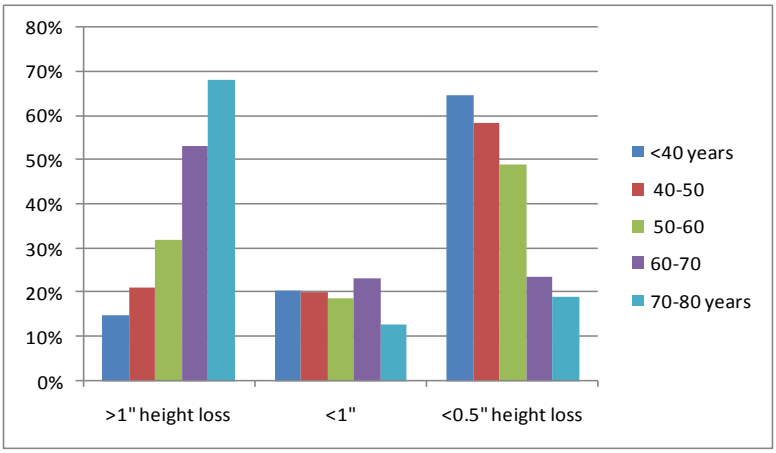


Table 3: The Bar Diagram (B) (below) represents Table 3

It demonstrates a high incidence of severe height loss (>1") & fragility fractures in older women. R^2 for height loss >1" is 0.999 and fragility fractures is 0.969.

Age	>1" height loss	<1"	<0.5" height loss	Fragility #s	High Vel #s	No #s
<40	15%	20%	65%	7%	12%	81%
40-50	21%	20%	58%	6%	19%	75%
50-60	32%	19%	49%	16%	16%	68%
60-70	53%	23%	24%	24%	13%	63%
70-80	68%	13%	19%	31%	18%	51%

(B)

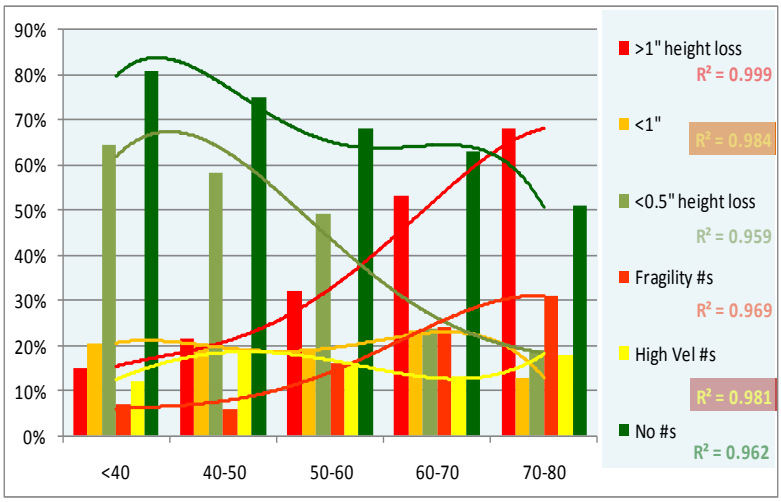


Chart 1: Height Loss of >1" in women aged 40 to 60 is associated with lower T-scores (Chart 1). R^2 values observed were 0.174 for Mild Height Loss <1" (567 women) and 0.166 for Severe Height Loss >1" (599 women)

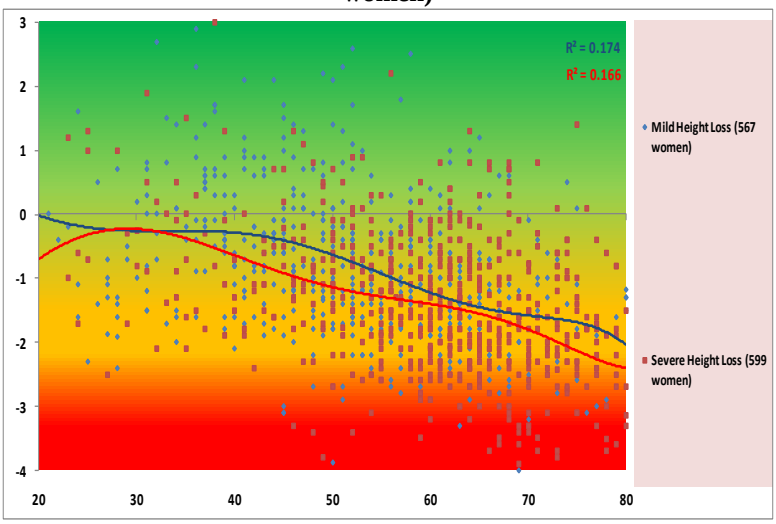


Chart 2: Of note, in Chart 2, women with Mild Height Loss (<1") having no fragility fractures (403 women) had highest T- scores. Women with Severe Height Loss (>1") with fragility fractures (105 women) had the lowest T-scores

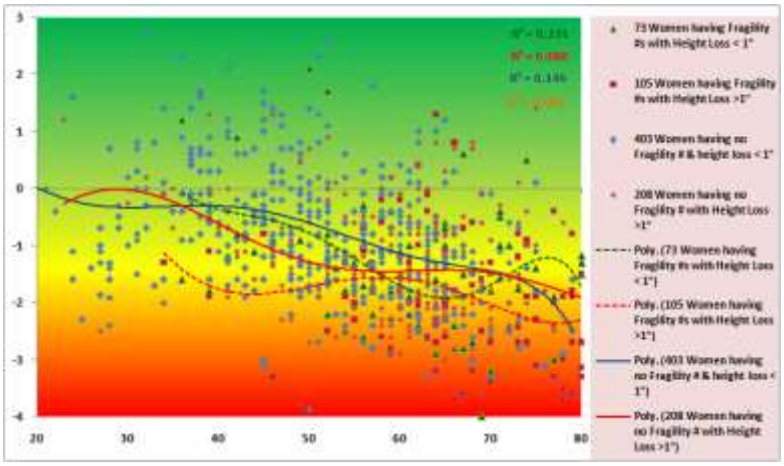
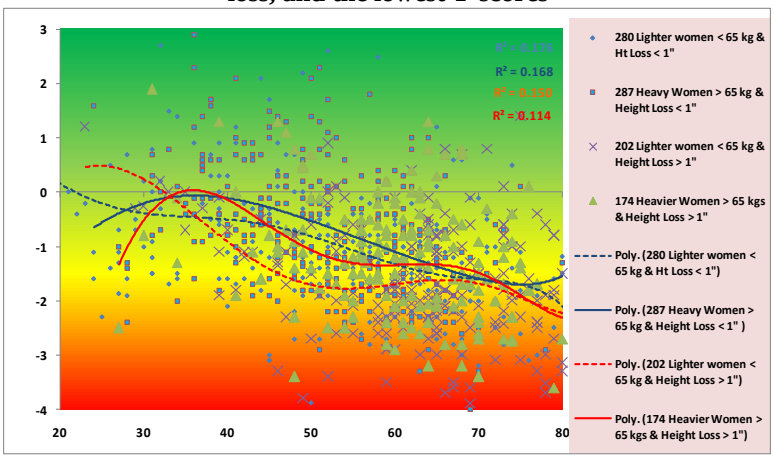


Table 4

No.	Age	Ht (in yrs)	Present Ht (yrs)	Wt (kg)	BMI	T-score Rt Heel	Ht loss	Past Menopause	Falls	Fragility Fx	Fragility Fx	High Velocity Fx	any Fx
287	51.5	159.6	159.3	70.0	29.2	-0.69	0.3	0.9	32/287 (11%)	33/48/206	13%	15%	72%
202	63.4	156.4	155.3	55.6	24.8	-1.66	2.0	1.6	23/202 (11%)	62/31/108	31%	15%	53%

No.	Age	Diet Ca scores	Smoking	Past Menopause	Grip Power Ever	Chair Test	Chair Test
287	51.5	3.5	0.02	0.9	2.4	6/229	2.6%
202	63.4	3.5	0.01	1.6	2.6	3/164	1.8%

Chart 3: Chart 3 demonstrates, 287 heavier women aged 40 – 60 years, who suffered mild height loss, had much stronger bones evident by their higher T-scores, than 202 women who were light and had severe height loss, and the lowest T-scores



Statistical Analysis: R^2 is a parameter indicating goodness of fit of the model. The value of R^2 lies between 0 & 1. High R^2 indicates good correlation

Discussion

QUS Ultrasound of the heel is a well-known technique for studying bone density and is widely used. It is relatively safe, inexpensive, does not involve ionizing radiation, is portable and is a non-invasive technique for the assessment of bone mineral density, particularly suitable for use in screening programmes[8,9,17,10].

Its utility in detecting osteoporosis has been compromised due to absence of serious effort at utilizing its qualities and eliminating its fallacies.

It is well known that QUS Ultrasound helps predict fracture risk independently of Dexa[18,19,20]. The term "established osteoporosis" includes the presence of a fragility fracture[21].

Validated heel QUS devices predict fractures in postmenopausal women (vertebral, hip and overall fracture risk) and in men 65 and older (hip and non-vertebral fractures).

Two large studies of elderly women found that low calcaneal ultrasonic variables (BUA and SOS) were able to predict increased hip fracture risk with similar accuracy to BMD measurement by DXA[18,19].

Investigators have shown simple scores incorporating clinical risk factors for prediction of fragility fractures and bone status, assessed by using quantitative ultrasound of the calcaneum[15,16,18].

Of particular significance in the detection of osteopenia or osteoporosis, is the possibility of an impending fragility fracture. Thus association with clinical risk factors is an important aspect in assessments made for osteoporosis. This has been appreciated in recent studies using the FRAX Tool (Fracture Risk Assessment Tool).

FRAX is a diagnostic tool used to evaluate the 10-year probability of bone fracture risk. It was developed by the WHO Collaborating Centre for Metabolic Bone Diseases at Sheffield University[22].

FRAX integrates clinical risk factors and bone mineral density at the femoral neck to calculate the 10-year probability of hip fracture and the 10-year probability of a major osteoporotic fracture (spine, forearm, hip or shoulder fracture)[23].

Clinical risk factors assessed include a prior fragility fracture, parental history of hip fracture, current tobacco smoking, long-term use of glucocorticoids, rheumatoid arthritis, other causes of secondary osteoporosis and daily alcohol consumption.

Among the various risk factors linked to Osteoporosis & increased fracture risk besides advancing age, and early menopause in young women, are hormonal disturbances and thin built women or those with low body weight and history of fracture/s.

Traditionally, age, weight, oestrogen deficiency and occurrence of fractures have been held responsible for decrease in bone density. These factors have been used to derive algorithms and scoring systems to decide need for further steps in managing osteoporosis and risk of fractures.

For e.g., The NOF (National Osteoporosis Foundation) guidelines for BMD testing[24,25,26] are based on the following well known principles:

- In Women aged 65 and older and men age 70 and older;
- In postmenopausal women and men age 50-69, when you have concern based on their risk factor profile;
- In those who have had a fracture, to determine degree of disease severity.

ORAI (Osteoporosis Risk Assessment Instrument), 2000 proved better than the National Osteoporosis Foundation guidelines at targeting BMD testing in high-risk patients[27].

It is a simple algorithm based on age, weight and current oestrogen use, having shown a sensitivity of 93.3% and a specificity of 46.4% for selecting women with low bone mineral density. The sensitivity for selecting women with osteoporosis was 94.4%[60].

The ORAI supports selective DXA testing in the following:

- In women aged 65 years or more,
- In women aged 45 years or more who weigh less than 60 kg, and
- In women aged 55-64 years who weigh 60-70 kg and are not taking oestrogen.

The OST score (Osteoporosis Self-Assessment Screening Tool), 2007, is a much simpler score. It has been established as highly sensitive and specific in women[7].

The score is calculated by subtracting the age of the patient in years from the weight in kilograms and multiplying the result by 0.2. The OST scores ranged from -6 (greatest risk) to 16 (least risk). The cut off of an OST score of <2 pointed towards a high risk of fracture.

The USOFRA study has come out with an additional clinical risk factor, namely detection of Severe Height Loss (>1") not in use by the WHO backed FRAX tool (2008), the NOF guidelines, the ORAI or the OST score.

We theories that in females aged 40-65, detection of Height Loss>1" from known height at the age of 20 or so, coupled with low body weight <65 kgs, and QUS heel T-score< -1.0 are at high risk of fragility fractures and need to be managed actively for osteoporosis.

Height loss may be the result of postural variations, muscle group weakness, disc degeneration, narrowing of the joint space, kyphosis and other spinal deformities. The above mentioned conditions have been excluded in this study.

Height Loss >1" has been shown to be associated with Osteoporosis in Post-menopausal women in earlier studies. Ht loss <1" was more often attributed to degenerative disc disease.

2-3 studies demonstrated >1" height loss attributed to spine fractures[28,29,30].

In a study aimed to clarify associations between height loss, bone loss and the quality of life (QOL) score among general inhabitants of Miyama (a rural Japanese community), a significant positive association was identified between height change and change rate of BMD at the lumbar spine after adjusting for age[28].

In this study there is a strong correlation between severe height loss & low T scores (<-1.0).

This study strongly demonstrates height loss >1" is a significant clinical finding. It should alert us to the possibility of onset/existence of osteoporosis. This will help prevent problems associated with established osteoporosis.

The social impact of using this simple observation has significant benefits. Its use as a screening tool in routine checks by clinicians will go a long way in the early diagnosis and prevention of a silent disease like osteoporosis.

This study found that elderly women with significant height loss were at increased risk for osteoporosis.

Similar to the development of osteoporosis, height loss also has an onset around 45-50 years and continues as age advances.

An important finding is height loss even in younger women.

However height loss is not currently used in osteoporosis risk assessment tools. This simple tool could be used to detect osteoporosis.

Our study may have some limitations as we have measured long term height loss, using the self-reported height of the individual and the present measured height[29].

Nevertheless our study has a positive outcome and perhaps this is our strength.

In our study we found that height loss was a useful predictive tool and alerted us to evaluate the patient further for osteoporosis.

Conclusions

In this study of 1136 pre- & post-menopausal women between 2008 and 2015, it has been demonstrated that Height Loss more than 1" is a significant risk factor and when clubbed with other risk factors including low QUS heel readings and low body weight, a high incidence of fragility fractures has been observed.

The study indicates that Severe Height Loss in women aged 40 years and above is a valuable clinical risk factor for osteoporosis. Its use as a screening tool in routine checks by clinicians will go a long way in the early diagnosis and prevention of a silent disease like osteoporosis.

Biography

Dr. Amod Pal Singh[1] is a Senior Orthopedic Surgeon & Medical Director at Uma Sanjeevani Hospitals. He has specialized in arthroscopy, knee surgery, shoulder surgery & total joint replacement. He is working in this field from last 30years in Delhi/ NCR.

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