The impact of the Hologic versus the Indian Council of Medical Research(ICMR) database in diagnosis of osteoporosis among South Indian subjects from India with Low impact Hip fractures

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Background

HOLOGIC- NHANES III DATABASE

Osteoporos Int (1990) 0:468–489 © 1990 European Foundation for Osteoporosis and the National Osteoporosis Foundation

Osteoporosis International

Original Article

Updated Data on Proximal Femur Bone Mineral Levels of US Adults

A. C. Looker[1], H. W. Wahner[2], W. L. Dunn[2], M. S. Calvo[3], T. B. Harris[3], S. P. Heyse[3,4], C. C. Johnston Jr[5] and R. Lindsay[7]

- National Health and Nutrition Examination Survey (NHANES III, 1988-94)

SEX	HIP BMD (gm/cm²)
MALE	1.041 ± 0.054
FEMALE	0.942 ± 0.122

- 14,646 men and women aged 20 years and older using dual-energy X-ray absorptiometry

Based on Caucasian data

OSTEOPOROSIS IN INDIA

Osteoporos Int (2010) 21:2115–2123 DOI 10.1007/s00198-010-1188-3

ORIGINAL ARTICLE

Race/ethnic differences in bone mineral densities

A comparison of bone mineral density between Caucasian, Asian and Afro-Caribbean women.

ORIGINAL ARTICLE

Comparative study of bone mineral density, calcium, and vitamin D status in the Gujarati and white populations of Leicester

Review Article

Indian J Med Res 127, March 2008, pp 263-268

Osteoporosis in Indians

N. Malhotra & A. Mithal

Original Article

BMD Reference Standards Among South Asians in the United States

Alexander Melamed,[1,4] Eric Vittinghoff,[2] Usha Sriram,[3] Ann V. Schwartz,[2]

Lower bone mineral density in Indians compared to caucasians

Population based Reference Standards of Peak Bone Mineral Density of Indian Males and Females

ICMR BULLETIN

ISSN 0377-4910 April 2011 Vol. 41, No. 4

Veena Shatrugna, A.C.Ammini, Nikhil Tandon, Ravinder Goswami, Nandita Gupta, Eesh Bhatia, Vijaylakshmi Bhatia, Rashmi Shah, Lalita Saverdekar, Rakesh Mittal, Ajit Mukherjee, Ajith Mathur, Neeta Kumar.

- NIN, Hyderabad
- AIIMS, New Delhi
- SGPGIMS, Lucknow
- NIRRH, Mumbai

Sex	n	Mean BMD±SD (gm/cm²)		
		Hip	Forearm	Spine
Male	404	0.966±0.131	0.611±0.052	0.976±0.105
Female	404	0.901±0.111	0.538±0.044	0.954±0.095

- An ICMR multi-center community based study,
- 2001 to 2006
- Aimed to determine the peak bone density at hip, spine and forearm for healthy Indian
- Males and females aged 20 -29yrs.

Based on Indian data

Aims & Objectives

- To assess the agreement between the Hologic Database(HD) and the ICMR database(ICMRD)
  - In defining normal and subnormal BMD
  - In diagnosing osteoporosis in subjects with low impact Hip fracture.
- To arrive at a cut off of BMD and T scores which have a high sensitivity of predicting fracture using both databases.

Materials & Methods

- A Cross-sectional study
- Study period - Jan 2010 – Mar 2013
- Study population:
  - GROUP 1 – Low impact Hip fracture
  - GROUP 2 - Hospital Database without fracture
  - GROUP 3 – Healthy postmenopausal women from the community
- Sample Size

For studying agreement between HD &ICMRD

551 subjects

(Agreement - 0.6, expected agreement - 0.5 , power - 80% and level of significance- 5%)

For calculating the BMD cut off which best predicts the risk of Hip Fracture

316 cases and 312 controls

(sensitivity - 80%, specificity - 70%, Precision - 5%, confidence limit - 95%)

Methodology

- The DXA scans - Hologic QDR 4500 Discovery A densitometer.
- Data regarding Age, Sex, BMD.
- T-score of Hip were computed using Hologic and ICMR databases.
- BMD sub-categorisation was based on WHO Classification.

- Normal - T score ≥ -1
- Osteopenia - T score -2.5 < T <-1
- Osteoporosis - T score ≤ -2.5

Weighted Kappa was used to look at the agreement between Hologic and ICMR databases.

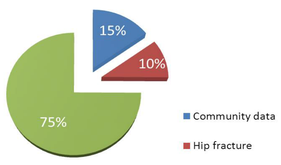
Receiver operating characteristics (ROC) curve was plotted using different cut-offs of BMD and T scores, which could best predict the Hip fracture risk.

SAS 9.1.3 version was used for Data analysis.

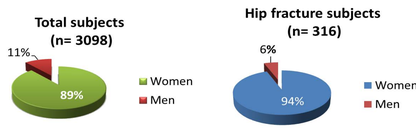
Results

Demography

- Total subjects - 3098
- Hip fracture subjects - 316
- Hospital data - 2321
- Community data - 461
- Mean age - 60.1 ±7.6yrs



SEX DISTRIBUTION



Distribution of Hip BMD according to Hologic and ICMR database

HOLOGIC DATABASE	ICMR DATABASE			
	NORMAL	OSTEOPENIA	OSTEOPOROSIS	Total
NORMAL	1307	1	6	1314
OSTEOPENIA	271	994	2	1265
OSTEOPOROSIS	2	96	297	395
Total	1580	1091	305	

20% cases categorized as osteoporosis by HD were reclassified as osteopenia by ICMRD

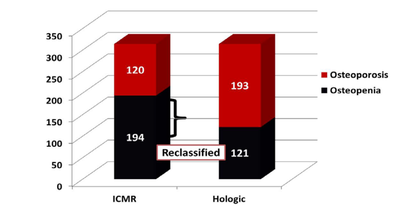
Weighted kappa – 0.82, CI 0.80 – 0.83
ALMOST PERFECT AGREEMENT

Agreement between HD & ICMRD in Hip fractures

ICMR Database	Hologic Database		
	Osteopenia	Osteoporosis	Total
Osteopenia	121	73	194
Osteoporosis	0	120	120
Total	121	193	314

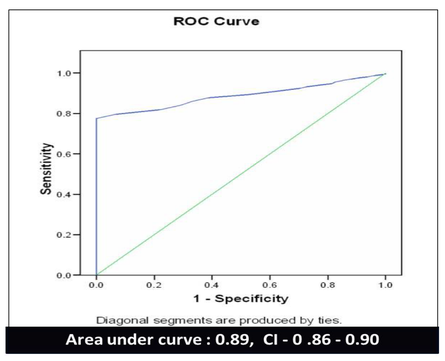
kappa – 0.65, CI 0.62 – 0.67
SUBSTANTIAL AGREEMENT

Comparison of Hip BMD between HD and ICMRD in subjects with hip fracture



23% (n=73) categorized as osteoporosis by HD were reclassified as osteopenia by ICMRD

ROC curve of BMD in relation with fracture using hospital data as controls

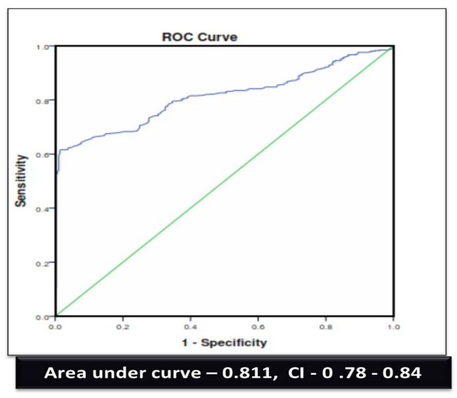


Area under curve : 0.89, CI - 0 .86 - 0.90

Cut offs for predicting HIP fracture risk (Hospital control)

- BMD: 0.681 gm/cm² (sensitivity 82% & specificity of 71%)
- T SCORE HD: - 2.1 (sensitivity 82% & specificity of 69%)
- T SCORE ICMRD: - 2.0 (sensitivity 82% & specificity of 70%)

ROC curve of BMD in relation with fracture using community data as controls



Area under curve – 0.811, CI - 0 .78 - 0.84

Cut offs for predicting HIP fracture risk (Community controls)

- BMD: 0.651 gm/cm² (sensitivity 80% & specificity of 65%)
- T SCORE HD: - 2.4 (sensitivity 81% & specificity of 62%)
- T SCORE ICMRD: - 2.2 (sensitivity 80% & specificity of 65%)

Discussion

- Agreement between the ICMRD and HD in categorization of BMD was "perfect" overall and "substantial" in Hip fracture subjects.
- About 20% subjects defined as osteopenia according to ICMRD were reclassified as osteoporosis by HD.
- ROC derived BMD cut offs for predicting the risk of Hip fracture were in the osteopenic range (T-score -2 to -2.4).

Sensitivity - 80% & Specificity - 70%

- This could imply the importance of assessing other risk factors affecting bone health while making therapeutic decisions.
- Incorporating FRAX - INDIA in clinical decision making may help in better management of patients.

Limitations

- Other Risk factors predisposing to Hip fractures were not assessed in this study.

Reference

- Makker A, Mishra G, Singh BP, Tripathi A, Singh MM. Normative bone mineral density data at multiple skeletal sites in Indian subjects. Arch Osteoporos 2007;3:25–37.

Conclusion

- Use of ICMR database may lower the categorization into osteoporosis in Indians.
- Therapeutic decision may be considered even at osteopenic range (-2.0 to -2.4).
- However, prospective studies are needed to further validate our findings.

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