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Letters to the Editor

Dear Editor,

The authors of the short communication titled “Cross sectional study of osteoporosis among ladies of Armed Forces” by Maj Tripti Agrawal published in MJAFI 2013; 69:168–171 must be complimented on drawing the attention of Armed Forces medical community towards wide prevalence of osteoporosis in India. Unfortunately, the study lacks credibility in many aspects due to serious deficiencies in the study design, data handling and execution which are highlighted as follows:

1. Conflict of interest: The study has been sponsored by a pharmaceutical company, Elder Pharmaceuticals, which manufactures and markets anti-resorptive drugs used in treatment of osteoporosis. Although the authors disclosed the sponsorship, they have not declared it as a potential “Conflict of Interest”. It is a common practice nowadays for pharmaceutical companies to organize camps similar to this study to promote their drugs, but this is the first time results of such a camp have been published. A potential conflict of interest exists and, unfortunately, none of the possible safeguards, including testing of equipment on a control group, were utilized by the authors.
2. Equipment used: Although the authors have declared that they used an automated equipment utilizing quantitative ultrasound (QUS) at a single site (Calcaneus), they failed to specify the manufacturing company, the model used or the technology utilized for same. There are multiple options available for BMD estimation utilizing quantitative ultrasound – dry systems, non-imaging water bath systems or imaging water bath systems. All these technologies have their limitations and an assessment across different technologies is not comparable. Also, since the skeletal involvement is variable in osteoporosis, single site measurement using QUS is a matter of concern.
3. Lack of adjustment for Body Mass Index (BMI): Broadband ultrasound attenuation is utilized in most QUS systems, but it is prone to relatively high measurement errors and is dependent on BMI and bone size. BMI is an important determinant of BMD and can be easily measured. In addition, ultrasound transmission will vary depending in the thickness of subcutaneous tissues. However, no effort was made to measure or make any adjustments for BMI in this study- potentially leading to significant measurement errors.¹
4. Comparability to WHO standards: WHO utilizes DEXA based measurements in classification and diagnosis of Osteoporosis. DEXA and QUS base measurements are not comparable. Also, there is no consensus in interpreting

QUS results for peripheral BMD measurements at present.²

5. Screening test conducted in a not-at-risk population group: Although osteoporosis is most prevalent in post-menopausal ladies, the study population comprised predominantly of pre-menopausal ladies (Not-at-risk population group). The reason for conducting such a screening study in a not-at-risk population is not clear. Furthermore, the study population had alarmingly high prevalence of osteopenia and osteoporosis in this not-at-risk group. The authors have failed to dwell upon possible reasons for such an unusually high prevalence. A possibility of an error in the QUS equipment can't be completely excluded. Also, the sponsors for the equipment did have a conflict of interest, as brought out earlier.
6. Recruitment bias: Participants in this study were volunteers who may have been inclined to seek out health information provided by the camp. This creates a bias towards recruitment of individuals who show greater awareness and response to health related issues.
7. Pregnancy and lactation: Although majority of the women were from the reproductive age group (108 out of 158 in 35–44 year age group), no data was collected about whether any of the women were pregnant or lactating. Pregnancy and lactation can possibly be a major confounding factor in this age group.
8. Sampling errors: Sample groups not comparable: Sample sizes across various ages were not comparable with the least likely affected age group (35–44 years) being the largest group ($n = 108$) and the most likely affected age group (55–64 years) being the smallest group ($n = 8$). Genetic and racial differences as well as community and individual variations in lifestyle across diverse population groups in army are possible additional confounding factors which were ignored in this study.
9. Cost effectiveness: It is quite well established that the use of QUS examinations as a screening test at population level before a definitive assessment with DEXA is not a cost-effective strategy.^{1,3} Therefore, the authors' conclusion to recommend QUS as a screening test for osteoporosis is quite contentious.
10. Important modifiable risk factors have been ignored in data collection including calcium and vitamin D deficiency, sedentary lifestyle, smoking, excessive alcohol and caffeine intake.
11. Nothing has been mentioned on type of questionnaire included to record information on sociodemographic characteristics: What type of questions were included closed or open ended, what language was used? In any

epidemiological study, the response to questions is also determined by the type of questions asked.

12. Confirmatory tests: Although QUS was used as a screening test for osteoporosis, it has not been disclosed by the authors if the ladies were subjected to more accurate DEXA after a positive quantitative ultrasound examination to confirm the diagnosis. Was any treatment offered to ladies suffering from osteopenia or osteoporosis?

To conclude, there are serious methodological errors in this study with ethical concerns in form of conflict of interest. The role of quantitative ultrasound as a screening test for osteoporosis remains questionable in light of current evidence. The aim of doing such a study is not clear as effectiveness of interventions in asymptomatic populations is questionable.

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Reply

Dear Editor,

On behalf of the authors, I thank the readers for the deep interest and scholarly analysis of the article and for providing a well researched addendum which will help in my future endeavours. My reply is as below:

1. Conflict of interest: Agreed, potential conflict of interest does exist, howsoever author had been honest to mention the sponsorer. However sponsorer had already been supplying via valid contract calcium combination named "Shelcal" all over AFMS hospital.
2. Equipment used: The equipment used was a non-imaging water bath system which had been standardized before conduct of the camp. It is not possible to apply gold standard test as screening test especially if they are not cost effective and possess problems of easy availability, accessibility, portability, feasibility in camp scenario. It has been brought out in the study that calcaneal QUS is a potential screening tool for diagnosing osteopenia and osteoporosis in the background various merits; besides it is being used by various studies utilizing same WHO T-score.
3. Lack of adjustment for BMI: Point taken, however since weight or body mass of the individual had been found to be related to Bone Mineral Density in the available literature, therefore it was studied as one of the influencing factor.
4. Comparability to WHO standards: The author did mention about the DEXA based measurements and the comparability of the same with QUS method as well as about the application of WHO T-score in interpreting the results.
5. Screening test conducted in a not-at-risk population risk: It was felt more relevant to the study the age bracket

which is actually facing the crunch of child bearing as well as the household chores in the active years of life when the actual brunt of such silent diseases starts and the same has been mentioned in the discussion.

6. Recruitment bias: Agreed, and therefore the honesty on the part of author to disclose that these are the results of study done during the camp.
7. Pregnancy and lactation: Agreed, but howsoever only ladies with non-pregnant and non-lactating status were enrolled for the study.
8. Sampling errors: It is to be reiterated that the study results were based on the inputs from the camp. Therefore no calculation of sample sizes was been done. Only relevant exclusion criteria were applied before analyzing the results. Howsoever, the camp activities were genuinely and fruitfully been utilized as pivot for raising health awareness about prevention of falls and fractures arising out of low bone mass.
9. Cost-effectiveness: Probably, it is not possible to apply gold standard test as screening test especially if they are not cost effective, possess problems of easy availability, accessibility, portability, feasibility in camp scenario.
10. Important modifiable risk factors: Attention is drawn towards the various exclusion criteria considered in the study.
11. Agreed, the open-ended questionnaire was prepared and was recorded by author in the form of interview.
12. Confirmatory tests: Screening does conclude with presence or absence of disease entity in question as brought by this study. The end result remains guiding the clientele towards adopting healthy lifestyle especially the affected ones.