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PART 1

Medicolegal Issues During the COVID-19 Pandemic

These are extraordinary times with extraordinary challenges, but even within this unique framework, the principles that doctors need to follow remain familiar.

This three-part series will review a few topics giving physicians concern:

Patient Confidentiality

IN THE OFFICE | Re-emphasize to staff, now, that PHI is never to be shared for non-work purposes in writing so you have proof that you did so. The COVID-19 pandemic has caused stress and shock, and there is simply too great a chance for a worried employee to vent that worry in a way that can identify a patient.

REMOTE WORK | HIPAA's rules on patient confidentiality still apply to a covered entity's employees, wherever work is performed. Any devices an employee will use should be strongly password-protected, and all PHI should be encrypted before it is transmitted. The connection must be secure. Talk to your IT person about levels of security that can be set up, such as two-factor authentication or having to login again after a period of absence.

If employees will be using personal computers, specifically deal with that, at least with written instructions and at best with a Bring Your Own Device agreement. It is essential to give any employees being sent home to work a formal written policy on maintaining PHI safely and to require them to sign that they received it. Employees must be cautioned about disposal of paper containing PHI. A cross-cut shredder should be used to destroy what minimal printing is done.

TELEMEDICINE | The Office for Civil Rights (OCR) is temporarily waiving penalties for the use of non-HIPAA compliant communication platforms and/or not having a Business Associates Agreement with the service used during the COVID-19 emergency. The service must not be public facing, but Skype, Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, and Zoom are acceptable.

You should inform the patient that what will be used is potentially not secure and get their express confirmation that they understand and agree. A standardized e-mail to which they reply affirmatively is a good approach for proof.

This is to last during the emergency, a period for which there is no end-date. You will need to stay alert for termination of the current emergency so as to not incur fines that will recommence for what would again then be a HIPAA violation.

This article was written by Dr. Medlaw, a physician and medical malpractice attorney.

Race & Osteoporotic Fracture Risk in Postmenopausal Women

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Prior research indicates that fractures, as the most clinically relevant endpoint of osteoporosis, are associated with excess disability and mortality. Although the Fracture Risk Assessment Tool (FRAX)—currently, the most widely used tool for fracture risk assessment—has improved fracture prediction rates upon those achieved with bone mineral density T-score method alone, its performance rate has been shown to vary among different study populations. "FRAX was calibrated with data from a predominantly Caucasian cohort," says Qing Wu, MD, ScD. "For US minorities, FRAX estimates are adjusted based on race-specific hip fracture incidence and race-specific mortality rates, but this is not empirically based. Nevertheless, the hypothesis that racial/ethnic differences that influence fracture risk were not adequately taken into account by FRAX has never been tested before. Determining whether FRAX performs differently in people with different race and genetic backgrounds would allow further improvement in fracture prediction."

Data Analysis

Using genomic data on nearly 24,000 postmenopausal woman participants of the Women's Health Initiative (WHI) study, Dr. Wu and colleagues conducted a study—published in the *Journal of Clinical Medicine*—that calculated genetic risk scores (GRSs) from 14 fracture-associated single nucleotide polymorphisms for each participant. FRAX without bone mineral density was used to estimate fracture probability. "We compared the FRAX-estimated, 10-year fracture risk with observed data among this patient population, stratified by race," explains Dr. Wu. "The ratio between FRAX-predicted and observed fracture probability was then calculated for each group (race and GRS). Multivariable Cox proportional hazard models were employed to assess the effect GRS and race had on time to the first fracture or mortality."

Probabilities by GRS & Race

The researchers found that FRAX significantly overestimated 10-year major osteoporotic fracture (MOF) probability among WHI participants. The most significant overestimations were seen among women who had a low GRS, with a FRAX-predicted probability of 6.02% versus an observed probability of 3.74%, or a predicted/observed ratio (POR) of 1.61, compared with PORs of 1.38 and 1.40 in the high and median GRS groups. "Compared with the low GRS group, the 10-year probabilities of MOF adjusted for FRAX score were 21% and 30% higher in the median and high GRS group, respectively," adds Dr. Wu. While FRAX also overestimated 10-year hip fracture risk in all GRS groups, PORs were similar across all three.

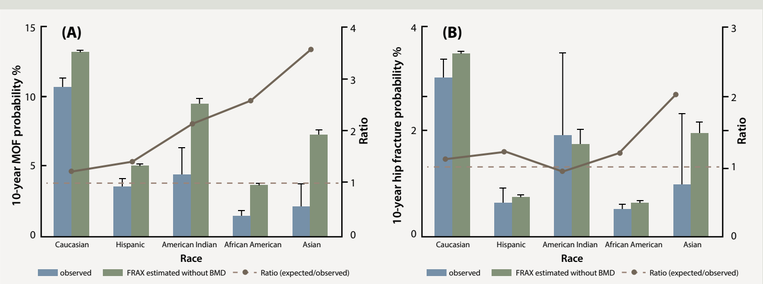
According to Dr. Wu, the study results "provide compelling evidence that FRAX significantly overestimates 10-year MOF probability in postmenopausal women across all racial groups (Figure)." The greatest overestimation was observed among Asian-American women, with a POR of 3.5, followed by African-American women, with a POR of 2.59. Interestingly, "Asian-American, African-American, and Hispanic-American women had 78%, 76%, and 56% lower risks of hip fracture, respectively, than did Caucasian women after the FRAX score was adjusted," explains Dr. Wu. FRAX also overestimated 10-year hip fracture risk among all racial groups, except American-Indian women, among whom the POR was 0.91.

Important Implications

"Fully integrating genetic profiling and racial factors into the existing fracture assessment model is very likely to improve the accuracy of fracture prediction," notes Dr. Wu. "Thus, developing racial/ethnic-specific, individualized fracture risk-assessment models may provide more accurate fracture risk assessment. Further studies, especially those including men, larger samples of minorities, and more comprehensive fracture-associated genetic variants, are warranted. In the meantime, our findings demonstrate that the effect of race in osteoporotic fracture prediction has not adequately been taken into account by existing FRAX models. The fracture risk derived from current FRAX scores should be interpreted with caution by clinicians."

Table Predicted Vs Observed Fractures

Observed versus predicted 10-year major osteoporotic fracture (A) and hip fracture (B) probability stratified by race. The dotted line indicates a relative ratio of 1 (reference line); ratio >1 indicates that FRAX overestimates fracture probability.



Abbreviations: BMD, bone mineral density; FRAX, Fracture Risk Assessment Tool; MOF, major osteoporotic fracture.

Source: Adapted from: Wu Q, et al. *J Clin Med.* 2020;9(1):E285.

In Case You Missed It

Social Inequality May Contribute to Poor Metabolic, Bone Health

Social factors might be significant contributors to coexisting metabolic syndrome (MetS) and osteoporosis (OP) in postmenopausal women, according to a study published in *Menopause*. Researchers used data from the Korea National Health and Nutrition Examination Survey (2008 to 2011) to identify 1,991 postmenopausal women aged 45 to 65 years. Associations of socioeconomic status-related factors and unhealthy lifestyle with the coexistence of MetS and osteopenia or OP were assessed. Overall, the prevalence of MetS+OP was 32.5%. In the MetS+OP group, the average number of MetS risk factors was 3.5, higher than that of normal and OP groups. Among women with MetS+OP, bone mineral density at all sites was significantly lower than in the normal and MetS group. Versus the other groups, calcium, phosphorus, vitamin A, riboflavin, and niacin levels were lowest in the MetS+OP group. Women with low income and low levels of education were more likely to have MetS+OP (odds ratio [OR], 1.97), while those with high income and high education were less likely to have MetS+OP (OR, 0.30) compared with the middle-income and middle-education group when controlling for other variables. "Social and political perspective approaches are required in this population for prevention and treatment of MetS and OP," the authors write.

Alone, Low Vitamin D Does Not Cause Osteoporotic Fractures

While low blood levels of vitamin D are associated with osteoporotic fractures, the link is not causative, according to an analysis published in *Clinical Chemistry*. Study investigators used Mendelian randomization to conduct a large-scale analysis of low vitamin D levels and osteoporotic fractures between 1981 and 2017. Participants included 116,335 randomly chosen 20- to 100-year-old white Danish people who underwent genetic and 25-hydroxyvitamin D testing as part of the Copenhagen City Heart and Copenhagen General Population Studies. The researchers identified 17,820 total fractures within their dataset. Compared with patients with vitamin D levels ≥50 nmol/L, total fracture hazard ratios for people with vitamin D levels of less than 12.5, 12.5 to 24.9, and 25 to 49.9 nmol/L, were 1.39 (1.21 to 1.60), 1.19 (1.10 to 1.28), and 1.03 (0.97 to 1.09), respectively. Corresponding hazard ratios for osteoporotic fractures were 1.49 (1.25 to 1.77), 1.25 (1.13 to 1.37), and 1.07 (1.00 to 1.15), while the corresponding hazard ratios for fractures of the hip or femur were 1.41 (1.09 to 1.81), 1.37 (1.18 to 1.57), and 1.09 (0.98 to 1.22). Notably, a genetic analysis indicated that every 1 increase in vitamin D allele score had a corresponding 3% lower vitamin D concentration and hazard ratios of 0.99 (0.98 to 1.00) for total fractures, 0.99 (0.97 to 1.00) for osteoporotic fractures, and 0.98 (0.95 to 1.00) for fractures of the hip or femur.

Atopic Eczema in Patients with Osteoporosis

Patients with atopic eczema have an increased risk for fracture, especially major osteoporotic fractures, according to a recent study published in the *Journal of Allergy and Clinical Immunology*.

Katherine E. Lowe, from the London School of Hygiene and Tropical Medicine, and colleagues performed a matched cohort study involving adults with atopic eczema matched with up to five individuals without eczema to compare the risk for any fracture and major osteoporotic fractures individually. Data were included for 526,808 individuals with atopic eczema and 2,569,030 without atopic eczema.

The researchers found that the risk for hip, pelvic, spinal, and wrist fractures was increased among those with eczema (hazard ratios, 1.10 [99% confidence interval, 1.06 to 1.14], 1.10 [1.02 to 1.19], 1.18 [1.10 to 1.27], and 1.07 [1.03 to 1.11], respectively). There was no evidence for increased proximal humeral fracture risk (hazard ratio, 1.06; 99% confidence interval, 0.97 to 1.15). With increasing eczema severity, increased fracture risk was noted, with the strongest correlation seen for those with severe eczema versus no eczema for spinal, pelvic, and hip fractures (hazard ratios, 2.09 [99% confidence interval, 1.66 to 2.65], 1.66 [1.26 to 2.20], and 1.50 [1.30 to 1.74], respectively). After adjustment for oral glucocorticoids, the associations persisted.

The substantial increase in the risk of spinal, hip, and pelvic fractures seen in those with severe atopic eczema should be of concern to physicians (more than double the risk of spinal fracture, 66% increased risk of pelvic fracture, and 50% increased risk of hip fracture) given the high morbidity and mortality associated with these fractures, the authors note.

Study results suggest that bone density screening guidelines should consider including individuals with more severe atopic eczema to prevent fractures, improve long-term quality of life, and reduce fracture-related health care costs.