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Vertebral fractures - is there a valid concept for (osteoporosis) treatment recommendation today?

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Objectives

Vertebral fractures are said to be the most common of all fragility fractures. They account for an estimated 700,000 of the 1.5 million osteoporotic fractures occurring annually in the United States alone.

Despite the importance of this fracture type, no optimal method or appropriate cut-off point for defining a vertebral fracture has yet been found. Depending on the method and the cut-off point chosen to define a vertebral fracture, fracture prevalence can differ two- to four-fold differences.

According to some studies only around 30% of vertebral deformations deemed warranting a fracture label are symptomatic. Furthermore, numerous studies have shown that patient-important outcomes – namely, back pain, disability, health-related quality of life, psychosocial problems and prediction of subsequent fractures – only have a significant association with moderate to severe vertebral deformities. Mild deformities, which represent about 50% of all vertebral fractures, are not or only poorly associated with such outcomes.

Methods

For our analysis we reviewed all major osteoporosis guidelines in the world regarding the following two questions:

1. Did the guideline provide any definition for vertebral fractures, i.e., define the method to examine x-rays and the criteria to be used to deem a deformation in a spine x-ray/bone densitometry scan as a vertebral fracture?

2. Was vertebral fracture considered an indication for initiation of osteoporosis drug treatment?

Additionally, we also reviewed the original 21 trials underlying the NICE appraisal on “Bisphosphonates in Osteoporosis” regarding the following two questions:

1. What assessment method and criteria were used for defining prevalent (baseline) and incident (new) vertebral fractures (baseline)?
2. Were clinical vertebral fractures recorded, and if yes, how were they assessed?

Results

The absence of a gold standard defining a “deformation” as a fracture is readily apparent in the osteoporosis guidelines: 31/43 guidelines do not provide any recommendation on the preferred method or diagnostic criteria and of the 12 guidelines that do, there is considerable variation regarding the recommendations. Remarkably, 28 of the 31 guidelines that fail to provide any definition on how to make the diagnosis still recommend initiation of pharmacotherapy in patients with a vertebral fracture.

Also, in the pivotal trials underlying the NICE appraisal on “Bisphosphonates in Osteoporosis”, there was no reliability or coherence to the way the pivotal pharmaceutical trials examined X-rays to decide whether or not patients had sustained a vertebral fracture. Furthermore, only 2 of the 21 trials used clinical vertebral fractures as their primary outcome.

Conclusion

Current definitions used by vertebral fracture scoring methods seem to be based on arbitrary cut-offs. If asymptomatic vertebral deformations are not truly clinically relevant, then using them as risk factors for future risk prediction may lead to overestimation of risk and, therefore, also to overtreatment. As anti-vertebral fracture efficacy is the central basis for the approval of practically all current and forth-coming osteoporosis drugs, it is of particular importance to tease out the true validity of this most widely endorsed rationale for the use of osteoporosis medication. We propose an individual patient data meta-analysis which re-analyses existing data, with independent, blinded adjudication of all vertebral fractures and separation of asymptomatic and symptomatic vertebral fracture outcomes. This will verify whether or not the asserted anti-vertebral fracture efficacy is valid.