ORIGINAL ARTICLE

Relationship between Presence of Mild Vertebral Wedges and Incidence of Clinically Significant Fractures and Episodes of Acute Axial Pain in Postmenopausal Patients

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ABSTRACT

Objectives: The aim of present study is to determine the incidence of major vertebral fracture (MVF) and episodes of acute axial pain in patients grouped according to the presence or absence of mild vertebral wedges (mVW). **Materials and Methods:** We conducted a 3-year retrospective longitudinal study following women over 65 with baseline radiological studies due to at least one episode of acute axial pain. Incidences of MVF and new episodes of acute lumbar or dorsal pain were compared according to whether or not they had mVW on their baseline radiographs. **Results:** A total of 1131 patients were followed over 3 years from the first episode of dorsal or lumbar pain. Of these, 716 had a radiological study with at least one mVW. In the group of patients with mVW, the incidence of clinically significant vertebral fractures was 1.6/1000 patient-years, while in the rest of patients, the incidence was 1.8/1000 patient-years ($P > 0.9$). Grouping patients according to their osteoarthritis severity, the cumulative incidence of dorsal and lumbar pain episodes along the period of observation, in patients with a spinal Kellgren-Lawrence's osteoarthritis degree I-II and III-IV were 19.8% (confidence interval [CI] 95% 12.10–27.49%) and 31.5% (CI 95% 18.27–44.72%), respectively ($P < 0.0001$). The density of incidence for both groups was 6.18 cases per 100 patients-year and 11.3 cases per 100 patients-year, respectively ($P < 0.0001$). **Conclusion:** Presence of mVW is not related to a significant increase in the incidence of either MVF or acute episodes of axial pain.

Key words: Mild vertebral body wedge, osteoarthritis, osteoporosis, risk of osteoporotic vertebral fractures

INTRODUCTION

Vertebral body deformities are defined as disruptions on the cortical surface of the bone and according to that, all deformities must be considered real bone fractures.[1-3] The importance of the radiological diagnosis of a vertebral fracture lays on the opportunity and advantages of starting secondary prevention of osteoporotic major vertebral fractures (MVF).[4-6] Genant *et al*. developed and validated a semiquantitative radiologic scale of vertebral body deformities, the Genant scale (GS), and classified them in 4°.[3,7] This simple scale has been used to stratify the severity of vertebral body fractures; however, the clinical significance of the mild vertebral wedge (mVW) has not been universally accepted. This lack of consensus is due to the fact that the deformity observed could be not only to an osteoporotic process but also to the result of cortical proliferation and intervertebral disc dehydration. Furthermore, the prevalence of mVW such as axial osteoarthrosis has been demonstrated to be higher in older women and they are not necessarily related to symptoms.[1,8,9]

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Osteophytes development and reduction of the height of an intervertebral disc are closely related to lumbar and dorsal osteoarthritis and they are not rare in women over 65 years old, the age from which osteoporotic vertebral fractures are more frequent. Due to that, most decisions related to starting secondary prevention of osteoporotic fractures are made according to vertebral body deformities of second grade and beyond.[5] Nevertheless, the mildest degree of vertebral fractures can be not only the radiologic feature of osteoarthritis but also a real vertebral fracture considering exclusively its physiopathology.[2] In any case, it is unknown to what extent mVW is related to a progression to an MVF or to a higher ratio of acute dorsal or lumbar pain episodes.

The aim of this study is to determine the incidence of MVF and acute episodes of dorsal or lumbar pain in postmenopausal patients according to the presence or absence of known mVW.

MATERIALS AND METHODS

To achieve our objectives, a historic prospective comparative study was conducted. Registries of female patients who consulted in our emergency department (ED) due to nontraumatic lumbar or dorsal pain, older than 65 years old from June 2013 to November 2013, were identified using the electronic database of our institution. The condition of non-traumatic pain determined by the physician who filled out the clinical registry at the ED.

Inclusion criteria for choosing patients were as follows: Radiologic dorsal or lumbar study available before November 2013 with no vertebral deformity or a Genant's first-grade deformity,[3] radiologic dorsal or lumbar study available after November 2016, and absence of significative scoliosis (more than 20°).[10] The radiological study was used to classify patients at the beginning of the follow-up as carriers of an mVW (GS1) or as no deformities detected or degree zero of the (GS0). Epidemiological and demographic data were also collected as well as a Kellgren-Lawrence osteoarthritis spine assessment.[11]

The analysis of the radiologic studies performed was assessed by a single expert who was blind to the clinical registries. All chosen patient registries were followed up over 36 months from the time of their respective inclusion; hence, the incidence of dorsal or lumbar pain episodes was calculated using the events detected during the time period divided by the accumulated time of following of all patients included in the study.

Once the population to be followed up was chosen, we conducted a review of their health assessment records into the social security network by means of the software HORUS® (Consejería de Sanidad de la Comunidad de Madrid). This review includes the following registries: ED visits, primary care assessments, and specialized clinics consultations. Registries selected were those generated into the period of 3 years from the time of inclusion, and which were related to axial pain (dorsal or lumbar). Inclusion criteria for registries of lumbar or dorsal pain episodes were the absence of a traumatic mechanism of injury and that the assessment had been performed inside the social security health network. It is important to note, in relation to the latter, that in the Spanish health-care system, patients have free access to hospital and out-of-hospital emergency services. It should also be noted that the current protocol for the management of postmenopausal patients with lumbar and dorsal pain includes an X-ray of the spine.

For purposes of incidence measures, we considered the last contact to any social security health-care service as a confirmation of surveillance. Only the dorsal or lumbar pain episodes registered along the period of time from November 2013 to November 2016 were considered; hence, the pain episode used to include patients with spine radiological studies did not account for incidence determinations. During the retrospective follow-up, we analyzed all radiologic studies of dorsal and lumbar spine to determine the appearance of new vertebral body deformity in both groups to reclassify the patients. Dorsal vertebral bodies were studied from the sixth to the twelfth vertebral body. The entire management of data is summarized in Figure 1.

RESULTS

The inclusion criteria were achieved by 1131 patients. Table 1 summarizes the demographic and epidemiological data of all patients. Among them, in 716 (63.3%) patients at least one Genant first-grade vertebral deformity was identified (GS1). The rest were considered free of vertebral deformities (GS0) at the beginning of the follow-up. The average age in GS1 group was 72.2 ± 3.4 (mean ± standard deviation) years old while in GS0 group was 70.9 ± 3.1 years old. Kellgren-Lawrence degree I and II were present in the spine of 845 patients (74.7%).

Over the 3-year follow-up period, 32 patients from GS0 developed a mild Genant's vertebral body deformity and were reassigned to the GS1 group. Ten patients from GS0 and 14 patients from GS1 group developed a second-degree Genant's vertebral deformity. On the other hand, two patients from the GS0 group and four patients from the GS1 group developed a third-degree Genant's vertebral body deformity. Once the radiological diagnosis was established, patients were changed from their original follow-up groups. The proportion of evolution to a Genant's significant vertebral wedge degree (MVF) was 12/415 and 18/716 in GS0 and GS1, respectively ($P = 0.31$).

Considering the changes in the composition of both groups, the follow-up time was 13,222 and 26,398 months for GS0

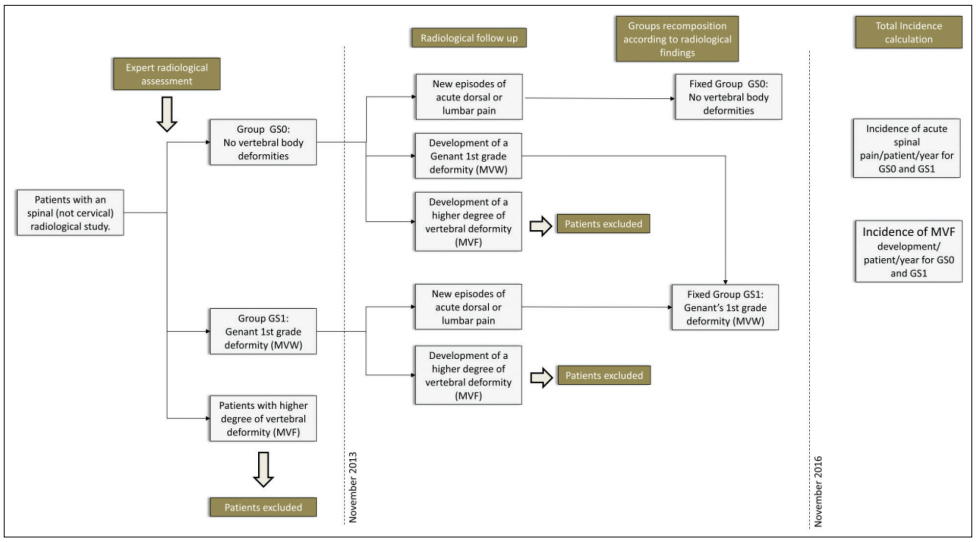

Figure 1: Patient follow-up flow summary. During the 3-year follow-up period, the appearance of radiological changes made it necessary to modify the original number of patients in each group. The presence of a MVF was a basal exclusion criterion, but its development throughout the follow-up period was accounted for in the calculation of incidences. mVW: Mild vertebral wedges or first-degree deformities of the Genant scale (GS). MVF: Major vertebral fractures or any other degree of deformity on the GS

Table 1: Composition of groups, demographical, and epidemiological data

Clinical or radiological feature	No vertebral body deformity (GS0) *n*=415	Mild vertebral body deformity (GS1) *n*=716	*P* value
Age±standard deviation	70.9±3.1	72.2±3.4	N.S.
Morbidities (%)			N.S.
Diabetes mellitus	35 (8.4)	59 (8.2)	
Hypertension	105 (25.3)	180 (25.1)	
Renal failure	21 (5.0)	45 (6.2)	
Cardiac insufficiency	26 (6.2)	40 (5.5)	
Chronic obstructive pulmonary disease	14 (3.3)	31 (4.3)	
Kellgren-Lawrence osteoarthritis severity (%)			<0.0001
I-II	190 (45.7)	655 (91.4)	
III-IV	225 (54.3)	61 (8.6)	
Patients who developed a GS1	32	-	N.S.
Patients who developed a level II or III Genant's deformity	2	4	N.S.
Follow-up time considering group changes (months)	13222	26398	-

GS: Genant scale

and GS1, respectively. The incidence of MVF in GS0 group was 1.6/100 patients-year and 1.8/100 patients-year in GS1 group ($P > 0.9$).

In the GS0 group, the cumulative incidence of dorsal or lumbar pain episodes was 7.2% per year (CI 95% 0–17.9%) and the incidence density was 7805 cases per 100 patients-year (CI 95% 7.69–7.91). In the GS1 group, the cumulative incidence of dorsal or lumbar pain episodes was 7.0% per year (CI 95% 0–15.3%) and the incidence density was 7318 cases per 100 patient-year (CI 95% 7.22–7.39). Both cumulative incidence and density of incidence differences were not statistically significant ($P = 0.7701$ and 0.5879, respectively).

Considering only patients with a first or second degree of Kellgren-Lawrence's scale of osteoarthritis, the cumulative incidence was 5.3% and 5.9% while incidence density was 0.1645 and 0.1055 cases per 1000 patient-year ($P = 0.365$). In the GS1 group, 655/716 patients presented a

spinal Kellgren-Lawrence's degree I or II. In the GS0 group, 190/415 patients presented the same osteoarthritis degree. Proportions of Kellgren-Lawrence degree I or II of osteoarthrosis in both groups were 45.7% in GS0 group and 91.4% in GS1 group ($P < 0.0001$).

Dividing patients according to their osteoarthritis severity, the cumulative incidence of dorsal and lumbar pain episodes along the period of observation, in patients with a spinal Kellgren-Lawrence's osteoarthritis degree I-II and III-IV were 19.8% (CI 95% 12.10–27.49%) and 31.5% (CI 95% 18.27–44.72%), respectively ($P < 0.0001$). The incidence density for both groups was 6.18 cases per 100 patients-year and 11.3 cases per 100 patients-year, respectively ($P < 0.0001$).

DISCUSSION

Episodic axial, lumbar, or dorsal pain cannot be attributed to osteoarthrosis as the sole causal entity due to two solid arguments: This type of pain occurs in all age groups, and in older patients, its relief does not reflect radiological changes.[12] The same reasoning cannot be applied to vertebral fractures. Acute pain is related to previously unidentified vertebral deformities and its resolution, partial or complete, follows the usual deadlines for a bone fracture in an elderly person.[8] Main problem is, however, what to be considered a true vertebral fracture.

The radiological definition of a mild vertebral fracture corresponds to the first degree of severity of the GS,[7] which in our study we have called mVW. To decide to start antiosteoporotic therapy, it is essential to determine whether or not a vertebral fracture has occurred.[5] In general and due to its relationship with the changes inherent in osteoarthrosis, mVW has not been considered as vertebral deformations that justify antiresorptive treatment. However, even with a correct radiological interpretation, it is not completely clear that mVW should be considered as clinically significant fractures.

Our results demonstrate that the presence of mVW is not associated with a significant change in the incidence of MVF. To our understanding, this absence of association allows us to continue considering them as clinically nonsignificant deformities. Therefore, the presence of mVW should not be a weighty factor when deciding to initiate pharmacological therapy for secondary prevention purposes.

Our study design has two relevant methodological limitations. There is a natural difficulty in linking the causality of a lumbar or dorsal pain episode in a patient with a vertebral body deformity when the localization of the collapse is far away from the topographic core of pain. To cope with that, the clinical information is quite useful; however, not all medical registries were fully completed. On the other hand, it is not possible to be sure that a new vertebral deformity detected by a radiological study during an acute dorsal or lumbar pain is chronologically related to the pain. We do not know for sure what the timing of the injury is since we have detected it due to the pain episode.

In spite of both limitations, our results demonstrate that the mild level of Genant's deformity is not associated with a higher incidence of dorsal or lumbar pain episodes than what we would have found in patients with no deformities. The previous studies demonstrated a relationship between the presence of any grade of vertebral body deformities and a higher number of axial pain episodes; however, they included not only mild wedges but also moderate and severe.[8,13,14] On the other hand, our study has been focused on the impact of mild vertebral body deformities comparing to those patients without them. The most reasonable interpretation of our results points out that the level of osteoarthritis is associated with a higher incidence of pain episodes instead of the presence of mild vertebral bodies deformities. This conclusion sustains the previous findings of Yu *et al.* who related this mild wedges to the process of aging.[1] However, in contrast to their conclusions, we have not found any association between the presence of mild vertebral deformities and progression to moderate or severe osteoporosis fractures along 3 years of retrospective follow-up.

In terms of management of a female patient older than 65 years old, who develops a mild vertebral body deformity with or without symptoms, our results support the decision to observe it instead of taking therapeutic initiatives or secondary prevention attitudes. Further studies with even more patients, with a longitudinal prospective design and aimed to obtain a radiological evolution of these mild deformities should be conducted. Until that, we consider back pain more related to osteoarthritis than to the presence of mVW and its radiological detection should not trigger any antiresorptive pharmacological measures with the intention of secondary prevention.

AUTHORS' CONTRIBUTION

Dr. Guillén-Astete participated in the whole development of the study. Dr. Vazquez-Díaz contributed to the global idea, analysis of data, and development of discussion. Dr. Pijoán-Moratalla and Dr. Quiñones-Torres contributed to the data gathering, data analysis, and development of discussion.

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How to cite this article: Guillén-Astete CA, Vázquez-Díaz M, Pijoán-Moratalla C, Quiñones-Torres JR. Relationship between the Presence of Mild Vertebral Wedges and the Incidence of Clinically Significant Fractures and Episodes of Acute Axial Pain in Postmenopausal Patients. Clin Res Orthop 2019;2(2):1-5.