



Vertebral compression fractures managed with brace: risk factors for progression

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Abstract

Purpose The aim of this study is to identify risk factors for vertebral compression fracture (VCF) progression in patients treated conservatively with a brace. Then, a case–control study was designed.

Methods All patients over 50 years old with diagnosis of thoracic or lumbar VCF (T5 to L5) in absence of underlying oncological process, treated conservatively with brace, and consecutively attended at our department from January 2017 to June 2021 were retrospectively selected for analysis. Patients missed for follow-up or dead during the first 3 months of follow-up were excluded.

Results Five hundred and eighty-two consecutive patients were recorded. Incomplete follow-up excluded 74 patients and other 19 died in the first three months after diagnosis, so 489 cases were finally analyzed. Median follow-up was 21 (IQR 13;30) weeks. Increased collapse of the vertebral body was found in 29.9% of VCFs with a median time to progression of 9 (IQR 7;13) weeks. Male gender (OR 1.6), type A3 fracture of the AOSpine classification (OR 2.7), thoracolumbar junction location (OR 1.7), and incorrect use of the brace (OR 3.5) were identified as independent risk factors for progression after multivariable analysis.

Conclusion Male gender, type A3 fracture of the AOSpine classification, thoracolumbar junction location, and incorrect use of the brace were identified as independent risk factors for VCF progression, which resulted in worse pain control, when treated with brace. Thus, other treatments such as percutaneous vertebral augmentation could be considered to avoid progression in selected cases, since collapse rate has been demonstrated lower with these procedures.

Keywords Fractures · Compression · Spinal fracture · Vertebral body · Retrospective studies · Follow-up studies

Introduction

The increasing life expectancy of the population is associated with a higher cumulative risk of osteoporotic fractures, which becomes a public health problem that entails 3.8% of the health budget in our country. It is estimated that

the number of fragile fractures will increase by 30% from 2019 to 2034 in our country [1]. It is a frequent pathology in fragile patients and may result in a painful and disabling condition in many cases. Most VCFs are treated conservatively (analgesics, bed rest, and/or bracing) with acceptable results. But some fractures progress or even collapse, which may result in chronic pain, deformity, and poor functional outcomes [2].

A previous study (unpublished data) showed a significant difference in the progression rate depending on the treatment modality. Thus, patients managed conservatively suffered re-fracture more frequently than patients treated with percutaneous vertebral augmentation. Several studies have focused on detecting those factors that may predict which patients are at risk of fracture progression. However, most of them have been performed on surgically treated patients (vertebroplasty or kyphoplasty) [3, 4] and only a few researchers have focused on patients treated conservatively [5–14].

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This study aims to identify variables that could represent risk factors for VCF progression in non-surgical patients managed with a brace to detect patients that may benefit from other surgical therapies. For that purpose, we have assembled the largest series published in the literature to date.

Materials and methods

A single-center, retrospective, case–control study was designed to identify factors increasing the risk of progression of a VCF following conservative management with an orthosis. The study was approved by the local Ethics Committee and was conducted in accordance with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Patients selection

All patients over 50 years old diagnosed with acute thoracic or lumbar VCF at levels T5 to L5, in the absence of underlying oncological process, treated conservatively and attended at our department from January 1, 2017, to June 30, 2021, were consecutively and retrospectively selected for analysis. Patients who missed follow-up and those who died during the first three months after diagnosis were excluded.

Non-surgical management consisted of analgesics and a back brace whenever the patient was incorporated -sitting or standing- until clinician's decision. The standard of care in our hospital involves bracing for all patients managed conservatively. This includes different types of devices, but the most frequently used are Jewett brace (T5-T10 levels) and thermoplastic thoracolumbar or lumbosacral orthosis (T10-L5 levels). The suitability for each patient is always secured before home discharge.

The first follow-up visit was achieved two months after the fracture. Then, depending on the evolution, another visit was programmed at three months (if the patient was still with the brace and/or pain) or at six months (if there was a good evolution). Each follow-up visit was accompanied by an imaging study.

Dependent variable

Progression fracture was defined as the increase in the height loss of the vertebral body, measured in the sagittal plane and at the point of maximal collapse, using plain X-ray, computed tomography, or MRI.

Independent variables

Epidemiological, clinical, diagnostic, and therapeutic variables were registered, including sex, age, history of cancer, chronic steroid use, history of previous vertebral fracture, prior diagnosis of osteoporosis, active use of anti-osteoporosis drugs (calcium, D vitamin, bisphosphonates, among others), mechanism of the fracture (fall -low energy trauma-, high-energy trauma, spontaneous fracture -no causative factor identified-, and overexertion -weight carrying or shoelace tying-), type of fracture according to AOSpine classification [15] (Fig. 1), location at the thoracolumbar junction, multiple fractures and correct use of the brace.

The pain was evaluated at 2-, 3- and 6-month follow-up visits. The onset of a new vertebral fracture in adjacent or distant levels was also checked at follow-up visits.

Statistical analysis

Numerical variables were described by the mean and standard deviation (SD) or the median and percentiles 25 and 75. The absolute and relative frequencies were used as the measure of description in categorical variables. The Student-T test and the Mann–Whitney U test were used to contrast the numerical variables. The Chi-square test was used in categorical variables.

For the multivariable analysis, the dependent variable considered was progression. The independent variables included were those associated with statistical significance in the univariable analysis and those considered relevant according to the scientific literature or the research team's experience. Independent risk and protective factors were identified using the Cox multiple regression method, and hazard ratios (HRs) with 95% confidence intervals (CIs) were calculated for each risk or protective factor. An automatic backward strategy was performed to retain the most relevant variables ($p < 0.05$) and create a parsimonious model. Calibration was tested using the Hosmer–Lemeshow test, and discrimination was checked through the area under the receiver operating curve (AUC ROC).

All statistical hypotheses were tested two-tailed. In all hypothesis contrasts the null hypothesis was rejected with a type I error or α error less than 0.05. Database information was processed and analyzed with StataCorp. 2019 (*Stata Statistical Software: Release 16*. College Station, TX: StataCorp LLC).

Results

A total of 582 consecutive patients were recorded. Incomplete follow-up excluded 74 patients, and 19 others died during the first three months after diagnosis, so 489 cases were finally analyzed.

AOSpine Classification [15]

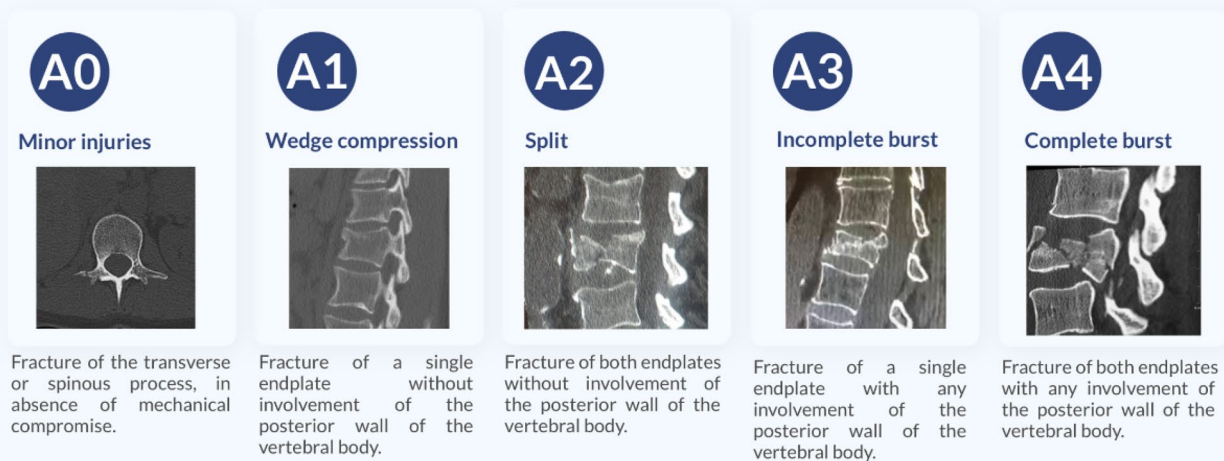


Fig. 1 AOSpine classification system for thoracolumbar compression fractures

Data showed female prevalence (71.8%) and mean age at diagnosis of 74.6 (SD 10.4) years old. The most frequent cause of fracture was a fall (60%), followed by a spontaneous mechanism (23.6%). The fracture was related to overexertion in 10.4% of cases and to high-energy trauma in 5.9%. Half of the fractures (55%) were localized in the thoracolumbar junction, while 22.5% of patients presented multiple fractures at diagnosis. According to the AO Spine classification, 76.7% of fractures were type A1, 20.9% were type A3, and only 2.4% were type A2. Patients used the brace for a median time of 12 weeks (IQR 9;18), and most (88.1%) followed the indications about its use. The median follow-up was 21 (IQR 13;30) weeks. Increased loss of vertebral body height was found in 29.9% of VCFs with a median interval from initial fracture to the diagnosis of progression of 9 (IQR 7;13) weeks. The new vertebral fracture rate was higher in the progression group (13% vs. 8.5%), but no statistically significant difference was observed ($p=0.121$). The occurrence of progression was associated with the persistence of pain at 3-month follow-up (46.9% vs. 28.3%; $p < 0.001$).

Factors associated with the progression of VCFs are shown in Table 1.

For the multivariable analysis, the maximal model included: age, sex, osteoporosis therapy, mechanism, AOSpine classification, thoracolumbar junction, and correct use of the brace. When applying the backward strategy, the final model retained the sex, AOSpine classification, thoracolumbar junction, and correctness in using the brace as variables independently associated with the progression of a VCF. (Table 2).

Discrimination and calibration of the model were satisfactory, with an AUC ROC equal to 0.693 and a comparison between the observed and expected frequencies in deciles with a p-value in the Hosmer–Lemeshow test of 0.968 (Fig. 2 and Table 3). No association could be found with age, fracture mechanism, previous history of oncologic disease or osteoporosis, chronic steroids use, previous fracture, multiple fractures at diagnosis, or active treatment with anti-osteoporosis drugs.

Discussion

Male gender, type A3 fracture of the AOSpine classification, thoracolumbar junction location, and incorrect use of the brace were identified as independent risk factors for VCF progression when treated with a brace. This complication was associated with worse pain control at the 3-month follow-up.

Progression or re-fracture of a considered VCF has received less attention in the literature than other complications, such as new adjacent fractures. However, the incidence of progression varies from less than 1% up to 63% depending on the series [3, 4, 16–18], with a cumulative rate of 10% [3]. In a previous study (unpublished data), almost 30% of the patients managed conservatively showed this complication, and the rate was significantly higher than the observed in patients managed surgically with vertebroplasty or kyphoplasty ($< 5%$; $p < 0.001$). The ultimate risk is the collapse of the vertebra, provoking neurological complications such as paraplegia [19]. Besides that, patients that presented

Table 1 Comparison of the VCF progression and non-progression groups

FACTOR	Progression group (n = 146)	Non-progression group (n = 343)	p value
Mean Age, yr (SD)	76.6 (9.22)	73.8 (10.70)	0.005
Gender Male, n (%)	50 (34.25)	88 (25.7)	0.053
History of cancer, n (%)	30 (20.5)	66 (19.2)	0.739
Chronic steroid treatment, n (%)	18 (12.3)	49 (14.3)	0.565
Previous fracture, n (%)	35 (24.0)	94 (27.4)	0.431
Osteoporosis-diagnosis, n (%)	52 (35.6)	108 (31.5)	0.373
Osteoporosis-therapy, n (%)	53 (36.6)	97 (28.6)	0.084
Mechanism of fracture, n (%)			0.071
Spontaneous	37 (25.3)	78 (22.8)	
Fall	95 (65.1)	198 (57.9)	
Overexertion	9 (6.2)	42 (12.3)	
High-energy trauma	5 (3.4)	24 (7.0)	
AO Spine classification, n (%)			< 0.001
A1	95 (66.0)	258 (81.7)	
A2	2 (1.4)	9 (2.9)	
A3	47 (32.6)	49 (15.5)	
Multiple level, n (%)	28 (19.2)	82 (23.9)	0.252
Thoracolumbar junction, n (%)	93 (63.7)	176 (51.3)	0.012
Median bracing duration, wk (IQR)	15 (11;22)	12 (9;16)	0.004
Correct use of brace, n (%)	114 (78.1)	310 (92.5)	< 0.001
Median follow-up, wk (IQR)	23 (14;34)	20 (12;28)	0.016

Bold values indicate the $p < 0.05$

Italic indicate the value for subgroups

IQR: interquartile range; SD: standard deviation; wk: week; yr: year

Table 2 Multivariate logistic regression analysis

FACTOR	ODDS RATIO (95% CI)	p value
Sex (male)	1.583 (1.001–2.501)	0.049
AO Spine classification		
A1	Reference category	
A3	2.686 (1.649–4.374)	< 0.001
A2	0.530 (0.109–2.577)	0.432
Thoracolumbar junction (yes)	1.712 (1.113–2.634)	0.014
Correct use of brace (yes)	3.488 (1.913–6.362)	< 0.001

Bold values indicate the $p < 0.05$

VCF progression in the present study reported worse control of pain than those who did not show the complication, a result in accordance with other authors [2]. The pain was not included in the analysis of risk factors since it is considered a consequence but not a cause of progression.

Two main factors affect the vertebral body from a biomechanical point of view. The cortical bone and the bone mineral density (BMD). Most risk factors of progression revolve around these two variables. In patients treated with percutaneous augmentation surgery, the risk increases when

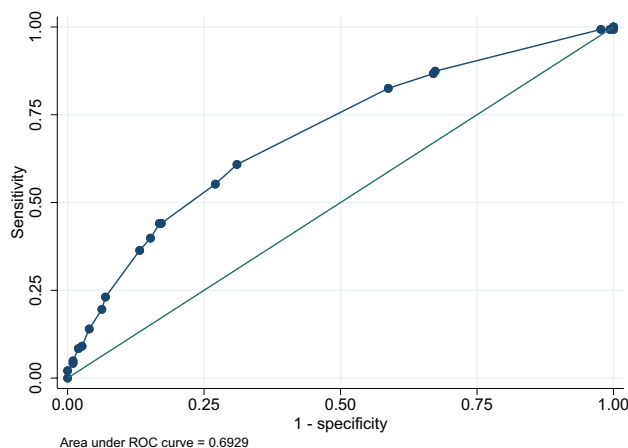


Fig. 2 Receiver operating characteristic curve analysis of the model for VCF progression

the fracture locates in the thoracolumbar junction, and the vertebra shows preoperative intravertebral cleft (IVC), there is a solid lump cement distribution pattern, preoperative severe kyphotic deformity exists, and when vertebral height restoration is higher (this latter, in kyphoplasty procedures)

Table 3 Calibration

Group	Prob	Observed	Expected	Total
2	0.1695	18	19.6	117
3	0.2441	7	8.0	33
5	0.2590	31	29.8	115
6	0.3541	8	7.1	20
7	0.3561	16	16.4	46
8	0.4842	30	28.5	61
9	0.5494	13	11.9	22
10	0.8383	20	21.7	32

Deciles of estimated probabilities and corresponding observed vs expected frequencies

Number of observations: 446

Number of groups: 8

Hosmer–Lemeshow $\chi^2(6) = 1.36$

Prob > $\chi^2 = 0.9680$

[3, 4]. Even though research is less prolific when considering conservative management, some shared variables, such as thoracolumbar junction fractures [8, 11, 13] and the presence of IVC [11], have been identified. Other studied risk factors are age [11], morphological type of the fracture [6, 11, 13], posterior wall involvement [5, 8, 14, 20], vertebral instability [14], MRI signal intensity changes [7, 9, 10, 13], and total 25-hydroxy vitamin D levels upon admission (in postmenopausal women) [14]. The influence of sagittal spinopelvic configuration has also been analyzed, but no relationship has been evidenced [21].

It is well-known that age increases the risk of osteoporosis and sarcopenia, and osteoporosis is the leading cause of BMD loss. Only one study has detected that it is also associated with a higher progression rate when conservative management is selected [11], an outcome that was not confirmed in the present study. Thus, Goldstein et al. described an increase of 0.5% in height loss every one year. The presence of old fractures has also been correlated with age, but it has never been identified as a risk factor for progression, a result that is similar to the one hereby obtained [8, 11].

The influence of patient gender is controversial since no authors have found a relationship with fracture progression (even in samples with a higher proportion of males) [11]. The multivariate analysis identified the male gender as an independent risk factor for progression in the present study. It should be considered if those male patients that attended our hospital with a VCF suffered a more severe grade of osteoporosis (and that is the reason why they underwent the fracture), were misdiagnosed with osteoporosis, if they incorrectly used the brace, if they were older, or if a mix of those factors coexisted. Mean age, rate of thoracolumbar junction location of the fracture, type A3 fracture, and correct use of the brace were similar when comparing males and

females. However, the diagnosis of osteoporosis was confirmed in 18% of males and 38% of females in this sample. This may not be representative of our population since the prevalence of osteoporosis in the European Union is 6.6% in males and 22.1% in females (6.8 and 22.6% in Spain, respectively) [22]. Thus, a sampling bias must be considered to cause the result.

An association between a confirmed diagnosis of osteoporosis and progression was not observed in the present study, but a marginal association was found when considering antiosteoporosis drug use ($p = 0.052$ in the multivariable analysis). Some studies have evidenced that teriparatide treatment decreases the progression of osteoporotic VCFs [17, 23]. However, the results hereby obtained are contending. The percentage of patients diagnosed with osteoporosis and those undergoing active treatment or prophylaxis was similar, regardless of the progression or not, so the difference may be explained because of the sample size. It is also noteworthy the absence of a correlation between progression and chronic steroids use since it is well-known that it decreases BMD and, therefore, predisposes it to bone fragility [24].

A non-traumatic mechanism of the fracture has been described as a risk factor in a single study in the literature [13]. Our series could not confirm this result. Despite we found a higher progression rate in those VCFs spontaneous or caused by a fall, no significant difference was observed. Besides that, the proportion of traumatic fractures (fall and high energy trauma) and non-traumatic ones (spontaneous and overexertion) was similar in patients that presented fracture progression and those who did not.

The above-mentioned variables are directly or indirectly related to BMD. Attending to the vertebral body's cortical bone, the fracture type must be outlined. Different classifications have been used in this regard, introducing a variability that prevents comparison [13]. Goldstein et al. [11] found that, according to the AOSpine classification [15], type A4 fractures collapsed the most often, followed by grades A3 and A2. No A4 fracture was registered in our series, but a significant risk was identified for A3 fractures when compared with A2 and A1 types. Thus, in both studies, A1 fractures were the least likely to progress, a finding supported by the presumed stability of this kind of lesion [11]. Moreover, type A3 fractures may be equivalent to posterior wall damage, and according to Denis' three-column theory, they may be considered unstable. So, these three biomechanical concepts (A3-A4 types, posterior wall involvement, and vertebral instability) are all related and seem to increase the risk of fracture progression [5, 8, 14, 20]. The proportion of A2 fractures was very small in our study (2.25% of all cases), with non-representative results. This is explained because A2 fractures are surgically treated with posterior fusion in a high percentage of patients.

Another important biomechanical detail is the spine segment where the fracture lays. The thoracolumbar junction is considered a fragile transition between the stable thoracic segment and the moving lumbar spine. The mechanical load that these specific vertebrae support may affect the risk of progression when the vertebral body is fractured. This is one of the most consistent risk factors identified in the literature, and the present study supports it [3, 4, 8, 11, 13]. The sagittal misalignment provoked by progressive spondylosis or previous fractures may also modify the mechanical load, affecting the risk of collapse. However, no effect was observed regarding the history of previous fractures in the present study.

Most studies include a brace in their treatment protocol [5, 8–10, 13, 14], but it is controversial the effectiveness in elderly population. Despite the variability in the type of orthosis, the shape, frailty, or the weight of the patients, this is the only research confirming that the incorrect use of the brace (shorter time than recommended or absence of use) increases the risk of fracture progression. It would be interesting to design further studies to analyze whether the election of the wrong type of brace may also be a risk factor for VCF progression. Thus, the lack of immobilization may lead to certain instability, hindering healing and precipitating collapse. Moreover, vertebral instability correlated with higher risk of collapse rate [14] and subsequent neurological deficit [25]. Duration of bracing was excluded from the multivariate analysis model since the more extended period with a brace in the progression group was a consequence of the complication rather than the cause.

Finally, we also found a significant difference in follow-up duration between the patients that showed VCF progression and those that did not. It is important to distinguish if a longer follow-up is the cause or consequence of the complication. The median time to detect progression was 9 weeks, in accordance with that reported by other authors who highlight progression within the first three months following the fracture [10]. In the present study, follow-up exceeded five months in the group without complication and six months in the progression group. Thus, longer follow-up could derive from the appearance of the new complication rather than be a risk factor for collapse. This is why this variable was not included in the multivariate analysis.

We report the most extensive study of risk factors for VCF progression following conservative management with a brace, compiling 489 patients. Both discrimination and calibration of the multivariate model hereby used were valid. However, two main limitations must be outlined. The first one refers to the study's retrospective design in a single institution, and the second one is the sampling bias of the population that has been detected. Likewise, it must be outlined the different imaging tests used to determine fracture

progression. Despite X-ray was used in most cases for both diagnosis and follow-up, in some patients the comparison was made with different techniques undertaken in different postures (supine or standing). Measurements were supervised by a radiologist when MRI or CT were used for follow-up, but a bias due to the position cannot be completely discarded. Finally, other parameters (including quantitative measurement of present ones) can be studied in further multicentric prospective studies.

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Author contributions RGG conceived the study, participated in its design, carried out data collection and drafted the manuscript; CO: carried out data collection and critical review of the manuscript for intellectual content; AR: participated in the design of the study and performed statistical analysis; she also revised the manuscript for intellectual content; AZ: carried out data collection and critical review of the manuscript for intellectual content; All authors read and approved the final manuscript.

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Data availability The datasets generated and/or analyzed during the current study are available at <https://doi.org/10.5281/zenodo.7558699> on request.

Declarations

Conflict of interest Raquel Gutierrez-Gonzalez, Celia Ortega, Ana Royuela, and Alvaro Zamarron declare that they have no conflict of interest.

Ethical approval The study was approved by the hospital Ethics Committee (reference 157/21) and was performed in line with the principles of the Declaration of Helsinki.

Consent to participate No informed consent to participate in the study was collected since the design was retrospective (the need for consent was waived by the Ethics Committee of Puerta de Hierro University Hospital).

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