

The development of a clinical decision making algorithm for detection of osteoporotic vertebral compression fracture or wedge deformity

Matthew Roman¹, Christopher Brown², William Richardson², Robert Isaacs², Cameron Howes², Chad Cook^{2,3}

¹Department of Physical and Occupational Therapy, ²Department of Surgery, and ³Department of Community and Family Medicine, Duke University, USA

The clinical diagnosis of an osteoporotic vertebral compression fracture (OVCF) is challenging and requires detailed assessment using comprehensive imaging methods. Further complicating matter is that the clinical sequelae associated with OVCF typically involves asymptomatic findings and variable pain patterns. The purpose of this study was to identify clinical characteristics and assessment findings that were associated with a diagnosis of OVCF. The study evaluated routine clinical findings in over 1400 subjects seen at an adult spine surgery clinic for thoracolumbar spine-related conditions within the years 2005–2009. All patients underwent a standardized clinical examination that included a self-report, observational, physical examination and imaging assessment. The diagnosis of OVCF was made after assessment of radiographic findings in sagittal alignment, vertebral body compression, and spinal canal dimensions. Data from the patient history and observational findings were then statistically analyzed and compared between those patients with a diagnosis of OVCF and those with an alternative diagnosis. Based on the results, a diagnostic support tool was created to predict the likelihood of OVCF. The most diagnostic combination included a cluster of: (1) age > 52 years; (2) no presence of leg pain; (3) body mass index \leq 22; (4) does not exercise regularly; and (5) female gender. A finding of two of five positive tests or less demonstrated high sensitivity of 0.95 (95% CI = 0.83–0.99) and low negative likelihood ratio of 0.16 (95% CI = 0.04–0.51), providing moderate value to rule out OVCF. Four of five yielded a positive likelihood ratio (LR+) of 9.6 (95% CI = 3.7–14.9) providing moderate value in ruling in the diagnosis of OVCF. Further validation is necessary prospectively to determine the value of these findings on a disparate sample of patients in other unique environments.

Keywords: Clinical prediction rule, Compression fracture, Lumbar spine, Osteoporosis, Radiograph

Osteoporotic fractures, including vertebral compression fractures are associated with significant mortality, morbidity,^{1,2} and low quality of life.³ Osteoporotic vertebral compression fractures (OVCFs) account for approximately one-half of all osteoporosis-related fractures⁴ and can affect as many as 40% of women within their lifetime or up to 13% all of individuals by the age of 50.⁵ By the age of 65, the incidence of an OVCF is alarmingly high, affecting 1% of women per year.⁵ Between the ages of 75 and 79, up to 2.9% of women demonstrate new vertebral fractures each year (2.4% in the USA).⁶ A single OVCF yields a four-fold increase in yearly risk

of further OVCFs in perimenopausal or postmenopausal women⁷ and a 25.7% likelihood of recurrent fracture (vertebral or otherwise) within 10 years of the primary fracture.⁸

OVCFs can lead to inordinate healthcare costs.⁹ Adjusted mean first year costs associated with OVCFs equate to an average of US\$15 000.⁹ Within the USA in 1995, primary OVCFs cost US\$5.1 billion (US\$6.3 billion in 2001) in healthcare expenditures.¹⁰ Costs may involve decreased productivity, medications, surgery, injection therapy, bracing,³ and physical therapy-related treatment that emphasize exercises to reduce falls risk, back strengthening exercises, and proprioceptive postural training.¹¹

Despite the known risks and costs, the clinical diagnosis of an OVCF is challenging. OVCFs are diagnosed by radiograph (or other forms of spinal

Correspondence to: Chad Cook, Department of Community and Family Medicine, Duke University Durham, NC, USA. Email: chad.cook@duke.edu

imaging such as a computed tomography scan) and routinely involve a careful assessment and recognition of the possibility of fracture by the attending physician and subsequent referral for imaging.⁴ The clinical course of an OVCF is variable.¹² Up to 67% of OVCFs are asymptomatic¹³ and the associative pain pattern in patients with symptomatic conditions is often inconsistent.¹² In some occasions, pain occurs before quantifiable imaging findings, which can further lead to misdiagnosis.¹⁴ Outside findings of low bone mineral density,⁵ there are *no unique* clinical signs and symptoms that are germane to an OVCF.

Early recognition of primary vertebral compression fractures is instrumental in limiting future morbidity. With the compelling incidence of recurrent fracture after primary diagnosis, effective disease management is essential in improving long-term outcomes of these patients. For the manual physical therapist treating the patient with a diagnosed vertebral compression fracture or with factors that are predictive of these fractures, effective management is essential. Consequently, the purpose of this study was to identify clinical characteristics and assessment findings that were associated with a diagnosis of OVCF. Clinical findings or clusters of findings may improve the manual physical therapist's ability to identify OVCF before treatment and when imaging is unavailable.

Methods

Study design and setting

The study was a retrospective, cross-sectional design. The study was performed in a division for adult spine disorders within the Department of Surgery of Duke University, which is a tertiary care institution in the USA.

Procedural guidelines

Procedural guidelines for this study followed the STARD standards for reporting of diagnostic accuracy set forth by Bossuyt *et al.*¹⁵ Briefly, the STARD standards are used to improve reporting processes for diagnostic accuracy studies and involve 25 items associated with topics germane in a typical case control design. Topics are oriented towards description of participant, statistical analysis, results, and conclusions of findings. The study protocol was approved by the Institutional Review Board of Duke University Health System.

Study participants

The study included 1448 consecutive patients seen at a spine surgery center at Duke University from 2005 to 2009. All patients with a lumbar-related disorder were eligible for the study if a clinical diagnosis was made and if imaging was performed or available for review. Patients were seen for a variety of signs and symptoms but in all cases, low back pain with or without leg pain was the patient's primary complaint.

Standardized clinical examination

All patients who attended the division for adult spine disorders within the department of surgery of Duke University received a standardized clinical examination that consists of self report, observational, physical examination, and imaging assessment. A standardized clinical examination that includes a minimum dataset was implemented in 2005 to improve outcome reporting and data capture at the institution. All data were prospectively collected by two orthopedic physicians. Both physicians were board certified orthopedic surgeons, one with 22 years of orthopedic surgical experience and the other with 4 years of orthopedic surgical experience.

The standard patient history included standard demographics capture and questions on the location, constancy, characteristics, and severity of pain in general and by location. In addition, questions regarding provocative movements (e.g. walking, sitting, or standing), alleviating movements (e.g. walking, sitting, rest, or standing), exercise frequency and participation, and previous treatment were captured. Standardized outcomes measures such as the SF12 (split by PCS and MCS) and the Oswestry disability index (ODI) were also captured.

The SF12 is a generic measure and does not target a specific age or disease group. The SF12 is a shortened version of the SF36 and is weighted and summed to provide an interpretable measure of quality of life.¹⁶ The SF36 has been used previously as a short and long-term measure of quality of life for patients with burst and wedge-related lumbar compression fractures.^{17,18} The ODI is a multidimensional scale and has been used to document changes in muscle activity, pain, psychological factors, and work status.¹⁶ The ODI has been used to evaluate pre- and post-surgical outcomes, as well as a benchmark for determination of treatment effectiveness. The data for the ODI provide both validation and standards for other users and indicate the power of the instrument for detecting change in sample populations.¹⁹ The ODI has been used for assessment of burst and wedge-related lumbar compression fractures.^{17,20}

The observational examination included a number of elements including gait (characterized as normal or abnormal, e.g. ataxic, wide based, or poor coordination). Physical examination tests included were a battery of motor, sensory, and reflex tests, use of the straight leg raise, range of motion assessment of the spine, and upper motor neuron assessment. Physical examination findings were not included in the clustered patient history and observational assessment. All clinical examination findings were inputted into a structured Excel compatible database that allows real-time Internet-based interface.

Diagnosis

The diagnosis of a lumbar compression fracture or a wedge deformity was made using standard radiographs or computed tomography scan. The currently accepted radiographic measurement parameters require assessment of findings in sagittal alignment, vertebral body compression, and spinal canal dimensions.²¹ These clinical measures, though commonly used, often demonstrate variability among physicians.²² Subsequently, although standardized radiographic markers were used during detection of a compression fracture or wedge deformity, it was clinical interpretation of these measures that served as the reference standard in this study.

Variables

The targeted variables for the study included predictive demographic, patient history and observational variables. Specifically, age, height and weight tabulated into body mass index (BMI), gender, presence or absence of a gait abnormality, report of regular exercise, report of decreased pain during sitting, presence of concomitant osteoarthritis, and presence or absence of buttock/leg pain were investigated. Age was selected as it has been associated with increased risk of compression fractures previously.²³ Risk of compression fractures for females, those with minimal exercise, and those with low body mass has also been reported.²⁴ The selection of the other variables was based on clinical experience. Although possible, in our experience, most patients with compression fractures do not experience radicular pain nor do they demonstrate neurological gait-related variations. Many of our patients exhibit concomitant osteoarthritis and report decreased exercise as a result. Further, many of our patients report relief with symptoms initially upon sitting with concomitant conditions such as stenosis.

Data analysis

Data downloaded from the Internet-based Excel system were transferred to SPSS 13.0 for Windows (SPSS Inc., Chicago, IL, USA). Descriptive statistics were captured and sequestered into groups of patients with and without a diagnosis of osteoporosis fracture or wedge deformity. Bivariate analyses between patients with and without a clinical diagnosis of osteoporosis fracture or wedge deformity were carried out. A *P* value of ≤ 0.05 was considered significant.

All 10 predictor variables were individually examined for diagnostic accuracy. Contingency tables (2×2) were used to calculate sensitivity and specificity, and likelihood ratios (positive likelihood ratio = LR+; negative likelihood ratio = LR-) for each predictive test item. Receiver operator characteristic curves were used to determine all possible cutoff values for the continuous measures of age and BMI.

The conditionally independent variables from the individual 2×2 analyses that yielded LR+ above 1.5 or LR- below 0.5 were retained for a backward stepwise logistic regression analysis. Variables with *P* values of 0.15 to exit the model and 0.10 to enter it were retained and were then inputted into 2×2 contingency tables that involved the conditions of one of five, two of five, three of five, four of five, and five of five positive findings. For each condition, sensitivity, specificity, and likelihood ratios were analyzed. In addition, in each condition, post-test probability measures were calculated using a pre-test probability of 2.6% (the prevalence of osteoporosis fracture or wedge deformity in this sample).

The study was powered using the regression values and the 10 predictor variables. Using Monte Carlo simulations, others²⁵ have reported that an *n* of 10–20 per predictor is appropriate for a boundary level per variable for regression analyses. This finding suggests that 100–200 patients would provide adequate values for the regression analysis, whereas larger numbers may be necessary to further reduce confidence intervals for the diagnostic accuracy statistics.

Results

The study captured 38 (2.6%) patients with a clinical diagnosis of osteoporosis fracture or wedge deformity and 1410 with a competing diagnosis. Significant differences in age ($p < 0.01$), gender ($P < 0.01$), marital status ($P < 0.01$), ODI ($P < 0.01$), and employment status were found between those with an OVCF and a competing diagnosis (Table 1).

Age > 52 years, BMI ≤ 22 , female gender, does not regularly exercise, sitting decreases pain, and no leg or buttock pain, had LR+ above 1.5 or LR- 0.50. Of the univariate findings, BMI ≤ 22 demonstrated the highest LR+ (2.3; 95% CI = 1.4–2.4), whereas age > 52 demonstrated the lowest LR- (0.14; 95% CI = 0.03–0.45). After the stepwise regression analysis, the variable *sitting decreases pain* was not retained.

The most diagnostic combination included a cluster of: (1) age > 52 years; (2) no presence of leg pain; (3) body mass index ≤ 22 ; (4) does not exercise regularly; and (5) female gender. Of the combinations, a finding of two of five positive tests demonstrated the lowest LR- (0.16; 95% CI = 0.04–0.51), providing value to rule out an osteoporosis compression fracture or wedge deformity. A combination of four of five tests yielded a LR+ of 9.6 (95% CI = 3.7–14.9). Because of the low prevalence, the post-test probability was only improved to 20.4% with the four of five test cluster.

Discussion

This study captured a cluster of five variables that were associated with the occurrence of an OVCF. Findings associated with: (1) age > 52 years; (2) no

presence of leg pain; (3) body mass index ≤ 22 ; (4) does not exercise regularly; and (5) female gender demonstrated clusters of both sensitivity and specificity that may be useful patient assessment when imaging has not been performed or is unavailable and when determining whether to use manual therapy on the targeted patient. A finding of two or fewer positive variables was moderately useful in ruling out the existence of a compression fracture because the sensitivity was high and the LR- was low. A finding

of four of five positive variables was useful in ruling in the existence of a compression fracture. Five of five was always associated with a fracture, although the sensitivity of the finding was extremely low. All five of the variables can be routinely gathered without expensive imaging methods or sophisticated testing procedures.

Previous studies have identified the relationship of increasing age and female gender towards the risk of a compression fracture.²⁶ For women, 10 year

Table 1 Descriptive statistics of the sample ($n = 1448$)

Descriptor	Diagnosed with osteoporosis compression fracture or wedge deformity ($n = 38$), mean (SD)/freq	Not diagnosed with osteoporosis compression fracture or wedge deformity ($n = 1410$)	P value
Age (years)	66.9 (10.9)	54.9 (16.0)	< 0.01
Gender	4 = male 34 = female	583 = male 827 = female	< 0.01
Race	32 = Caucasian 3 = black 0 = Hispanic 1 = Asian 0 = other	1153 = Caucasian 139 = black 18 = Hispanic 31 = Asian 14 = other	0.90
Marital status	25 = married 1 = single 3 = widowed 8 = divorced 1 = other	910 = married 177 = single 129 = widowed 83 = divorced 68 = other	< 0.01
Employment status	3 = full, part, or paid leave 3 = unemployed 0 = student 16 = retired 10 = disabled	469 = full, part, or paid leave 70 = unemployed 48 = student 400 = retired 276 = disabled	< 0.01
Educational status	1 \leq high school 15 = high school 2 = some college 5 = college degree 4 = graduate degree	33 \leq high school 317 = high school 325 = some college 343 = college degree 197 = graduate degree	0.14
Oswestry disability	25.1 (7.7)	21.1 (9.1)	< 0.01
SF12 MCS score	41.6 (5.9)	42.8 (6.0)	0.25
SF12 PCS score	45.4 (7.7)	47.0 (8.9)	0.28

Table 2 Validity of individual measures of osteoporosis fracture or wedge deformity

Test item	Sensitivity (95% CI)	Specificity (95% CI)	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)
Age > 52 years	0.95 (0.83–0.88)	0.39 (0.38–0.40)	1.5 (1.3–1.5)	0.14 (0.03–0.45)
BMI ≤ 22	0.38 (0.24–0.55)	0.83 (0.82–0.84)	2.3 (1.4–3.4)	0.74 (0.54–0.91)
Gender (female)	0.90 (0.76–0.96)	0.41 (0.41–0.42)	1.5 (1.3–1.6)	0.26 (0.10–0.60)
No gait abnormality	0.66 (0.50–0.79)	0.23 (0.22–0.23)	0.86 (0.65–1.02)	1.5 (0.91–2.2)
Does not exercise regularly	0.81 (0.65–0.91)	0.44 (0.43–0.45)	1.5 (1.2–1.6)	0.43 (0.20–0.80)
Sitting decreases pain	0.29 (0.27–0.32)	0.81 (0.79–0.83)	1.6 (1.2–1.9)	0.87 (0.82–0.92)
Concomitant Osteoarthritis	0.50 (0.35–0.65)	0.52 (0.51–0.52)	1.1 (0.70–1.4)	0.97 (0.67–1.3)
No leg or buttock pain	0.31 (0.16–0.49)	0.86 (0.85–0.87)	2.2 (1.2–3.6)	0.81 (0.58–0.97)

Note: Useful likelihood ratios appear in bold.

Table 3 Clustered findings for diagnosis of osteoporosis fracture or wedge deformity ($n = 1448$)

Clustered results	Sensitivity (95% CI)	Specificity (95% CI)	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)	Post-test probability of CTS (%)
1 of 5 positive tests	0.97 (0.89–0.99)	0.06 (0.06–0.07)	1.04 (0.92–1.1)	0.39 (0.07–2.1)	2.7
2 of 5 positive tests	0.95 (0.83–0.99)	0.34 (0.33–0.34)	1.4 (1.3–1.8)	0.16 (0.04–0.51)	3.6
3 of 5 positive tests	0.76 (0.61–0.87)	0.68 (0.68–0.69)	2.5 (1.9–2.8)	0.34 (0.19–0.46)	6.3
4 of 5 positive tests	0.37 (0.24–0.51)	0.96 (0.95–0.97)	9.6 (3.7–14.9)	0.65 (0.50–0.79)	20.4
5 of 5 positive tests	0.03 (0.01–0.08)	0.99 (0.98–0.99)	9.3 (1.4–60.2)	0.97 (0.92–0.99)	19.9

Note: Five findings are included in the rule: (1) age > 52 years; (2) no presence of leg pain; (3) body mass index ≤ 22 ; (4) does not exercise regularly; and (5) female gender. The associated post-test probability values are based on a pre-test probability of 2.6%.

increases in age lead to 2.0–2.3 increases in risk for OVCF.^{27,28} Osteoporosis is routinely associated with post-menopausal women.²⁹ Women make up 80% of diagnosed osteoporosis cases in the USA²⁹, and this population is the group that most commonly suffers from low or high energy compression fractures.² Low BMI has also been previously identified as a risk factor for OVCF.³⁰ Past studies have suggested 1.6–1.8 times greater relative risk of OVCF in patients with 1 BMI to 4 BMI incremental reductions compared to controls.^{28,31} Low BMI in comparison to overweight patients demonstrates a significant risk for vertebral fracture²⁶ and the combination of low BMI and low bone mineral density increases the magnitude of risks associated with this variable.³⁰

The role of physical activity and exercise as a protective effect for OVCF has been previously investigated by Sinaki and associates.³² Sinaki *et al.*³² demonstrated that back muscle strengthening led to a reduction of incidence of OVCF over a 10 year period. Exercises consisted of prone site-specific extension exercises, which have been investigated comparatively to flexion-based exercises and have shown superiority.³³ In indirect support of these findings,^{32,33} our study found that report of no exercise was associated with an increased risk of compression fracture.

Pain pattern associated with OVCF has been reported to be both variably distributed throughout the spine and a poor predictor of outcome.³⁴ Our study identified 31% of subjects who reported leg pain associated with their OVCF, in comparison to Doo *et al.*³⁴ who reported 43%. The variations are likely associated with the method in which the pain location data were collected. In our study, we asked a specific question associated with leg pain, whereas Doo *et al.*³⁴ used patient-generated pain drawings. In nearly all cases with Doo and colleagues,³⁴ the primary report of pain was in the thoracolumbar region more so than the leg. Consequently, our findings are likely similar in context.

To our knowledge, there is only one other study that has investigated the diagnostic accuracy of clinical findings to the incidence of OVCF. Jarvik and colleagues reported data on 833 patients with back pain at a walk in clinic that received plain film radiography.³⁵ Their findings suggest high likelihoods of OVCF in patients over the age of 70 and those with long-term corticosteroid use (although the sensitivity of this finding is very low). None of the data reported was useful in ruling out compression fractures.

For the manual physical therapist, these findings are potentially beneficial, specifically in environments where clinicians treat patients who have received no imaging. An OVCF is considered a relative contraindication for non-thrust manipulation³⁶ and an

absolute contraindication for thrust manipulation,³⁶ specifically since the stability of the compression fracture is always unknown without imaging. The findings of this study may be useful for manual physical therapists to refer to as needed when an OVCF is suspected.

Limitations

There are a number of limitations to the study. The radiographs used in the study did not involve longitudinal changes in vertebral condition; thus, there is a risk that the diagnosis of OVCF was made on an old compression fracture. Most OVCF are asymptomatic,^{37,38} consequently, there is a chance that the clinical findings could have been associated with a concomitant disorder, rather than the compression fracture. The spectrum of patients included those attending a spine surgery clinic and may not correspond with patients seen at other clinical environments or in typical healthcare screening settings. The variables for the clustered analysis were examined retrospectively and retrospective analysis has been identified as a potential for bias by the STARD initiative.¹⁵ Nonetheless, two recent meta-analyses that examined potential biasing factors for diagnostic accuracy studies^{38,40} have reported on the use of retrospective data, one indicating no difference than data that were captured prospectively and analyzed as such,³⁹ while the other indicating somewhat inflated diagnostic accuracy values.⁴⁰ Lastly, despite the use of currently accepted radiographic measurement parameters which required assessment of findings in sagittal alignment, vertebral body compression, and spinal canal dimensions, there is a risk of error in the physician's diagnosis, a risk that is prevalent with all diagnostic studies.

Conclusion

Clusters of clinical findings may be useful in ruling out and ruling in an OVCF in patients with back pain. Further validation is necessary prospectively to determine the value of these findings on a disparate sample of patients in other unique environments.

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