

ORIGINAL ARTICLE

Symptom Duration and Age as Predictors of Early Pain Reduction After Balloon Kyphoplasty for Osteoporotic Vertebral Compression Fractures: A Retrospective Cohort Study in Indonesia

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ABSTRACT

Background: Osteoporotic vertebral compression fractures (OVCFs) cause disabling pain and kyphosis. Balloon kyphoplasty (BKP) provides rapid stabilization, but predictors of early pain relief remain debated in Southeast Asian populations.

Objective: To identify clinical and radiological predictors of early pain reduction after BKP for OVCFs in an Indonesian tertiary referral cohort.

Methods: This retrospective cohort study analyzed 30 consecutive patients with OVCFs (age ≥ 50 years; bone mineral density T-score ≤ -2.5) treated with BKP at Dr. Mohammad Hoesin General Hospital, Palembang, Indonesia (January 2024–December 2025). Numerical Pain Rating Scale (NPRS) scores were recorded preoperatively and at discharge (24–48 hours). Seven candidate predictors (age, sex, T-score, kyphotic angle, symptom duration, treated levels, preoperative NPRS) were assessed with bivariate correlation and stepwise multivariable linear regression (screening $p < 0.25$).

Results: Mean age was 67.2 ± 7.39 years (range 54–82); 24 patients (80.0%) were women. NPRS decreased from 7.43 ± 0.77 to 2.80 ± 0.81 (mean reduction 4.63 ± 1.16 points; 62.3%; $p < 0.001$). Six variables were significant in bivariate analysis. Duration of complaints ($\beta = -1.881$; 95% CI -2.452 to -1.310 ; $p < 0.001$) and age ($\beta = -0.428$; 95% CI -0.831 to -0.025 ; $p = 0.039$) remained independent predictors ($R^2 = 0.723$; adjusted $R^2 = 0.702$; $F = 35.579$; $p < 0.001$). Asymptomatic cement leakage occurred in two patients (6.7%), without severe complications.

Conclusion: BKP was followed by substantial early pain reduction with few complications. Shorter symptom duration and younger age were independently associated with greater early relief, suggesting that earlier treatment may improve outcomes.

1. Introduction

Osteoporotic vertebral compression fractures (OVCFs) are a major global public health problem. They account for millions of new fragility fractures each year and cause physical disability, progressive axial deformity, cardiopulmonary restriction and premature mortality in aging societies.^{1,2} In the Global Burden of Disease Study 2021, fractures of the vertebral column of all causes accounted for 7,497,446 incident cases, 5,371,438 prevalent cases and 545,923 years lived with disability worldwide, with age-standardized incidence rates rising steeply after the sixth decade of life.¹ Involutional bone loss and postmenopausal estrogen depletion accelerate osteoclastic resorption in the axial skeleton, thinning the vertical trabecular struts, disrupting horizontal trabecular connectivity and increasing cortical porosity.³ In such weakened bone, the compressive loads of routine daily activities, minor forward flexion or low-energy slips can exceed the yield point of the vertebral body and cause anterior wedge collapse, biconcave endplate depression or crush deformity.^{4,5} Beyond the acute pain caused by periosteal tearing and endplate microfracture, untreated OVCFs alter anterior column biomechanics: the sagittal vertical axis shifts forward, and adjacent osteopenic

segments carry greater bending loads, which amplifies the subsequent fracture cascade.⁶

Historically, first-line management of symptomatic OVCFs without neurological compromise has been conservative, combining bed rest, opioid and non-steroidal anti-inflammatory analgesia, thoracolumbar bracing and physical rehabilitation.^{7,8} However, prolonged immobilization in older adults accelerates disuse osteopenia, with lumbar spine bone mineral decreasing by about 1% per week during bed rest,⁹ promotes paravertebral sarcopenia and predisposes frail patients to potentially life-threatening complications, including hypostatic pneumonia, deep venous thrombosis, pulmonary embolism, pressure ulcers, and gastrointestinal hemorrhage or renal insufficiency from systemic analgesia.^{8,10,11} Furthermore, between 10% and 40% of conservatively managed patients have persistent pain because of intravertebral micromotion, progressive kyphotic collapse or pseudarthrosis (Kümmell disease), which prolongs hospitalization and functional dependence.^{11–14} Percutaneous vertebral augmentation, comprising percutaneous vertebroplasty (PVP) and balloon kyphoplasty (BKP), changed the management of painful OVCFs by providing immediate internal stabilization through minimally invasive polymethylmethacrylate (PMMA) cementation.^{12,15–17}

Balloon kyphoplasty refines vertebral augmentation by introducing an inflatable bone tamp, transpedicularly or extrapedicularly, into the collapsed vertebral body before cement delivery.¹⁵⁻¹⁸ Controlled inflation of the balloon compacts the surrounding osteoporotic cancellous bone, elevates the depressed endplates toward their pre-fracture configuration, partially corrects segmental kyphosis and creates a low-resistance cavity.¹⁷⁻¹⁹ Higher-viscosity PMMA can then be injected at low manual pressure into this cavity, which reduces the risk of extravertebral venous or epidural cement leakage compared with high-pressure injection in conventional vertebroplasty.^{15,19} Recent systematic reviews, network meta-analyses and cohort studies, including the 2025 syntheses by Encalada et al., You et al. and Li et al., report that balloon kyphoplasty provides greater short-term and 12-month pain relief than non-surgical care, as well as greater vertebral height restoration, greater Cobb angle correction and lower cement leakage rates than standard vertebroplasty.^{12,15,16,20,21}

Despite the established overall efficacy of balloon kyphoplasty, the magnitude of postoperative pain relief varies considerably between patients.²²⁻²⁵ Single-center cohorts report residual back pain in 12.7% to 19.5% of patients after percutaneous kyphoplasty,^{26,27} and recent meta-analyses by Chen et al., Yang et al. and Li et al. estimate a pooled prevalence of about 16% to 19%, with risk factors pooled by Wang et al.; residual pain undermines functional recovery, delays hospital discharge and diminishes patient satisfaction.^{22-25,28} Earlier studies have proposed many candidate prognostic variables, including age, sex, baseline bone mineral density (BMD) on dual-energy X-ray absorptiometry (DXA), segmental kyphosis, fracture chronicity or symptom duration before surgery, the number of augmented levels, intravertebral vacuum clefts, thoracolumbar fascial injury and paravertebral muscle degeneration, but their relative independent contributions remain contested.^{26,28-31}

Most prognostic models for balloon kyphoplasty have been derived from Western European, North American or East Asian metropolitan centers,³²⁻³⁵ whereas data from Southeast Asian populations, and from Indonesian tertiary referral centers in particular, remain scarce.^{1,36} In archipelagic, lower-middle-income health systems such as Indonesia, patients with symptomatic OVCs often pass through tiered primary and secondary referral pathways, or undergo prolonged traditional non-operative care, before reaching a spine surgery center.^{37,38} As a result, preoperative symptom duration ranges widely, from acute fractures of about 2 weeks to chronic fractures of more than 30 weeks. Whether prolonged symptom duration and advanced age independently reduce early postoperative pain relief, when analyzed together with BMD T-score, kyphotic angle, number of fractured levels, sex and baseline pain intensity, has not been quantified in this population.

From a neurobiological and biomechanical standpoint, the transition from an acute osteoporotic vertebral collapse to a chronic symptomatic deformity is accompanied by changes in nociceptive signaling that may limit the pain relief achievable with PMMA augmentation.^{32,33,39} During the acute phase (typically the first 2 to 4 weeks after fracture), axial pain is thought to be driven mainly by peripheral nociceptive activation of unmyelinated C fibers and thinly myelinated Aδ fibers of the basivertebral nerve within the cancellous marrow and of the sinuvertebral nerve, which innervates the periosteum and posterior longitudinal ligament.^{33,40,41} Unconsolidated trabecular microfractures undergo continuous shear during changes in posture and release local inflammatory mediators, including prostaglandin E2, bradykinin, tumor necrosis factor-α

(TNF-α), interleukin-1β (IL-1β) and interleukin-6 (IL-6), which lower the firing threshold of peripheral nociceptors.^{40,42} When balloon kyphoplasty is performed within this acute window, cavity creation and PMMA interdigitation immediately arrest intertrabecular micromotion, and the exothermic polymerization of the methacrylate monomer, which reaches local temperatures of 50 °C to 60 °C, may thermally ablate intraosseous nociceptors, contributing to pain relief within 24 to 48 hours.^{32,33,35}

Conversely, when surgery is delayed into the subacute and chronic phases, two parallel processes may reduce the effect of mechanical stabilization alone.^{32,43} First, structurally, osteoclastic resorption and fibrous callus organization within the collapsed vertebra reduce its compliance and impede balloon expansion, while uncorrected anterior wedging transfers chronic tensile strain to the posterior thoracolumbar fascia, supraspinous ligaments and facet joint capsules.^{39,44,45} Second, neurobiologically, sustained high-frequency nociceptive input from an unstabilized vertebral fracture induces activity-dependent neuroplasticity in the dorsal horn of the spinal cord, characterized by phosphorylation of N-methyl-D-aspartate (NMDA) glutamate receptors, microglial and astrocytic activation, and loss of γ-aminobutyric acid (GABA)-ergic and glycinergic inhibitory interneurons.^{46,47} Once central sensitization and paravertebral myofascial fatigue are established, stabilizing the anterior vertebral body alone may not fully relieve the centralized pain state.^{27,39,46,48,49} Advanced age may add to this vulnerability through reduced descending serotonergic and noradrenergic pain inhibition,^{50,51} age-related paravertebral sarcopenia and myosteatosis of the multifidus and erector spinae muscles.^{27,39,48,49,52} Understanding how symptom duration, age, BMD T-score, sagittal kyphotic angle, number of fractured levels, sex and baseline pain severity behave in bivariate and multivariable models is therefore clinically relevant to spine surgery in Southeast Asia.^{45,53-55}

For these reasons, we reviewed 30 consecutive patients who had balloon kyphoplasty for OVCs at Dr. Mohammad Hoesin General Hospital in Palembang, Indonesia, to find out which clinical and radiological factors were linked to early pain reduction, and whether those factors might guide patient selection, the timing of surgery and what patients are told to expect.^{12,22,28}

2. Methods

Study design and setting

This single-center retrospective cohort study was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.⁵⁶ It included consecutive patients with symptomatic OVCs who underwent percutaneous balloon kyphoplasty at the Department of Orthopaedics and Traumatology, Dr. Mohammad Hoesin General Hospital, Palembang, South Sumatra, Indonesia, over 24 months between January 2024 and December 2025. Dr. Mohammad Hoesin General Hospital is the main tertiary academic referral center affiliated with the Faculty of Medicine, Universitas Sriwijaya, and serves a provincial catchment population of more than eight million residents in South Sumatra and neighboring provinces.

Participants and eligibility

Patients were identified through a systematic review of the institutional spine surgery registry, operating theater logs, picture archiving and communication system (PACS) spinal imaging archives and inpatient discharge databases from January 2024 to December 2025. During this period, 44

consecutive adult patients presenting with symptomatic thoracolumbar or lumbar vertebral compression fractures were screened for eligibility. Fourteen patients (31.8%) were excluded on predefined clinical and radiological criteria: four (9.1%) with pathological fractures secondary to metastatic carcinoma or multiple myeloma; three (6.8%) with burst fractures showing posterior cortical wall retropulsion and symptomatic neural canal compromise; two (4.5%) with active pyogenic or tuberculous spondylodiscitis or osteomyelitis at the index level; two (4.5%) with uncorrectable coagulopathy or anticoagulation that could not be interrupted; and three (6.8%) with incomplete perioperative pain records or loss to follow-up before the planned 4-week visit.

The analysis included 30 eligible patients with complete data (complete-case analysis) who met all six inclusion criteria: (1) age ≥ 50 years at surgery; (2) imaging-confirmed osteoporotic vertebral compression fracture with a DXA BMD T-score ≤ -2.5 according to the World Health Organization criteria;^{10,57} (3) persistent axial back pain refractory to initial conservative management and corresponding anatomically to marrow edema on fat-suppressed T2-weighted or short tau inversion recovery (STIR) magnetic resonance imaging (MRI);^{32,33} (4) treatment with percutaneous balloon kyphoplasty; (5) complete standardized preoperative and discharge Numerical Pain Rating Scale (NPRS) assessments; and (6) completion of at least 4 weeks of postoperative clinical and radiological follow-up.

Operative procedure

All balloon kyphoplasty procedures were performed by senior orthopedic spine surgeons using a standardized biplanar C-arm fluoroscopic protocol.^{32,58} Patients were placed prone on a radiolucent carbon-fiber spinal frame, with cushioned bolsters under the upper thorax and iliac crests to allow abdominal suspension and postural extension reduction of the fractured segment.^{58,59} Depending on cardiopulmonary status and the number of treated levels, procedures were performed under local infiltration anesthesia (1% lidocaine infiltrated down to the periosteum at the pedicle entry point) with monitored intravenous analgesia, or under general endotracheal anesthesia. Under anteroposterior and lateral C-arm guidance, an 11-gauge bone biopsy trocar was introduced transpedicularly (entering at the 10 o'clock position of the left pedicle projection and the 2 o'clock position of the right) and advanced into the anterior third of the fractured vertebral body while preserving the medial pedicle wall.⁵⁸ After withdrawal of the stylet, a working cannula was seated 3 to 5 mm anterior to the posterior vertebral cortex, a bone drill was used to create an intravertebral channel, and an inflatable bone tamp filled with iodinated contrast medium was inserted.^{18,58} The balloon was inflated incrementally under continuous manometric pressure control (typically up to 150–250 psi) and lateral fluoroscopic monitoring until satisfactory endplate elevation, cavity creation or cortical contact was achieved.^{17,18} After balloon deflation and removal, high-viscosity PMMA cement in its doughy phase was injected incrementally at low pressure through a calibrated bone filler until the cavity and the surrounding anterior and middle trabecular spaces were filled without posterior venous or canal extravasation.^{15,60,61} After complete cement polymerization, the cannulas were withdrawn, hemostasis was secured and sterile dressings were applied. Patients were mobilized with a thoracolumbar orthosis within 6 to 24 hours, assessed for discharge at 24 to 48 hours and prescribed standardized anti-osteoporotic therapy comprising elemental calcium (1,000 mg/day), cholecalciferol (vitamin D3, 800–1,000 IU/day) and an oral bisphosphonate during outpatient follow-up.

Outcomes and variables

The primary endpoint was early postoperative absolute pain reduction (Δ NPRS), defined as the difference between the preoperative pain score and the pain score recorded at hospital discharge (24 to 48 hours after the procedure): Δ NPRS = $\text{NPRS}_{\text{preoperative}} - \text{NPRS}_{\text{postoperative}}$.¹² Relative pain reduction was calculated as $(\Delta\text{NPRS} / \text{NPRS}_{\text{preoperative}}) \times 100\%$. Pain intensity was measured with the validated 11-point NPRS, scored from 0 (no pain) to 10 (worst imaginable pain), by trained clinical assessors blinded to the multivariable modeling hypothesis.^{53,62} Responder status was defined by three thresholds: achievement of the minimal clinically important difference (MCID; Δ NPRS ≥ 2.0 points), substantial clinical benefit ($\geq 50\%$ relative pain reduction) and high-magnitude response ($\geq 60\%$ relative pain reduction).^{63,64}

Seven candidate variables were extracted as potential prognostic factors: (1) age in years at surgery; (2) sex (female = 1, male = 0); (3) preoperative lumbar or femoral BMD T-score measured by DXA; (4) preoperative segmental kyphotic angle ($^{\circ}$), measured by the Cobb method as the sagittal angle between the superior endplate of the intact vertebra above the fracture and the inferior endplate of the intact vertebra below it on standing or lateral spinal radiographs;³³ (5) duration of complaints, in weeks from acute pain onset to surgery (also grouped as acute [≤ 4 weeks], subacute [5–12 weeks] and chronic [> 12 weeks]);^{32,33} (6) the number of vertebral levels augmented (one, two or three); and (7) the preoperative NPRS score. Secondary safety outcomes were intraoperative and 4-week postoperative complications: radiographic cement leakage (classified by anatomical compartment and symptoms), adjacent-level vertebral compression fracture, pulmonary cement embolism, new neurological deficit, and surgical site infection or spondylodiscitis.^{60,65}

Statistical analysis

Analyses were performed in IBM SPSS Statistics version 26.0 (IBM Corporation, Armonk, NY, USA) and checked in Python 3.11 (SciPy and statsmodels). Continuous variables were summarized as mean $\pm$ standard deviation (SD), range and 95% confidence interval (CI), and as median and interquartile range (IQR, 25th–75th percentile). Categorical variables were expressed as frequencies and percentages. Normality was assessed with the Shapiro–Wilk test (W statistic), and homogeneity of variance across symptom-duration subgroups with Levene's test; Δ NPRS was compared across the three subgroups with one-way analysis of variance (ANOVA). The preoperative-to-postoperative change in NPRS was tested with the paired Student's t test and the Wilcoxon signed-rank test (Z statistic), with the standardized paired effect size (Cohen's d_z = mean Δ NPRS / SD of Δ NPRS).

Bivariate associations between each candidate variable and Δ NPRS were quantified with Pearson correlation coefficients (r) for continuous variables, Spearman rank correlation coefficients (r_s) for the ordinal number of levels (and as a non-parametric check for the skewed duration of complaints), and point-biserial correlation coefficients (r_{pb}) for sex, each with its 95% CI and coefficient of determination (r^2). Candidate predictors with bivariate $p < 0.25$ were entered into stepwise multivariable linear regression (entry $\alpha = 0.05$, removal $\alpha = 0.10$) to identify independent prognostic factors.^{28–30} Model fit was evaluated with the omnibus F test, R^2 , adjusted R^2 and Cohen's f^2 ($f^2 = R^2 / [1 - R^2]$). Regression coefficients (β), standard errors (SE), t statistics, two-tailed p values and 95% CIs were tabulated, together with the parameters of the excluded covariates in the full-covariate model. Regression diagnostics included the variance inflation factor (VIF; < 2.5 taken as acceptable),

normality of studentized residuals, inspection for homoscedasticity and Cook's distance. Statistical significance was defined a priori as a two-tailed $p < 0.05$.

Prediction matrix

To illustrate the fitted model across the 0–10 NPRS range, predicted pain reductions were calculated for representative symptom durations (2, 8, 16 and 24 weeks) and ages (55, 65 and 75 years) (Table 5 and Figure 5A).^{28–30} In the final two-predictor model (adjusted $R^2 = 0.702$; $F(2, 27) = 35.579$; $p < 0.001$), duration of complaints ($\beta = -1.881$; $SE = 0.279$; $t = -6.738$; $p < 0.001$) and age ($\beta = -0.428$; $SE = 0.197$; $t = -2.173$; $p = 0.039$) were retained, with an intercept $\beta_0 = 16.841$. The predictions were calculated from the equation $\Delta NPRS = 4.63 - 0.0813 \times (\text{duration in weeks} - 11.57) - 0.0428 \times (\text{age in years} - 67.20) = 8.447 - 0.0813 \times \text{duration} - 0.0428 \times \text{age}$, which passes through the cohort means (duration 11.57 weeks, age 67.20 years, $\Delta NPRS 4.63 \pm 1.16$ points). Expected discharge NPRS scores and relative pain reductions were calculated relative to the cohort mean preoperative NPRS of 7.43 points, to support preoperative counseling and rehabilitation planning across the acute (≤ 4 weeks), subacute (5–12 weeks) and chronic (> 12 weeks) presentation windows.

Ethical approval

The study protocol was reviewed and approved by the Institutional Health Research Ethics Committee of the Faculty of Medicine, Universitas Sriwijaya and Dr. Mohammad Hoesin General Hospital, Palembang, Indonesia (Reference No. 2023/201). All clinical, radiological and surgical procedures were conducted in accordance with the 1964 Declaration of Helsinki and its later amendments, and written informed consent was obtained from all participants before surgery and for the inclusion of their anonymized data.

3. Results

Baseline characteristics

Thirty consecutive patients with imaging- and DXA-confirmed OVCFs who underwent balloon kyphoplasty met all eligibility criteria and completed the 4-week postoperative follow-up (Table 1; Figure 1). Mean age was 67.2 ± 7.39 years (range 54–82; 95% CI 64.44–69.96; median 67.00 [IQR 61.00–73.00]), with no evidence of departure from normality (Shapiro–Wilk $W = 0.968$; $p = 0.485$). Women accounted for 80.0% of the cohort ($n = 24$; 95% CI 62.7%–90.5%) and men for 20.0% ($n = 6$; 95% CI 9.5%–37.3%), a female-to-male ratio of 4.0:1.0, consistent with postmenopausal osteoporotic fragility (binomial $p = 0.001$). Preoperative DXA confirmed osteoporosis (T-score ≤ -2.5) in all 30 patients, with T-scores ranging from -4.6 to -2.5 and a mean of -3.29 ± 0.64 (95% CI -3.53 to -3.05 ; median -3.25 [IQR -3.80 to -2.80]; Shapiro–Wilk $W = 0.942$; $p = 0.103$). Preoperative standing or lateral radiographs showed a mean segmental kyphotic angle of $19.85 \pm 7.71^\circ$ (range 8.5–34.2°; 95% CI 16.97–22.73°; median 19.40° [IQR 13.80–25.60°]; Shapiro–Wilk $W = 0.959$; $p = 0.292$), indicating moderate wedge deformity before augmentation.

The duration of pain before surgery ranged from 2 to 38 weeks, with a mean of 11.57 ± 9.68 weeks (95% CI 7.96–15.18) and a median of 8.50 weeks (IQR 4.00–16.75); the distribution was right-skewed (Shapiro–Wilk $W = 0.864$; $p = 0.001$). By fracture acuity, 9 patients (30.0%) presented in the acute phase (≤ 4 weeks), 11 (36.7%) in the subacute phase (5–12 weeks) and 10 (33.3%) in the chronic phase (> 12 weeks). The mean number of augmented levels was 1.37 ± 0.56 (95% CI 1.16–1.57; median 1.00 [IQR 1.00–2.00]); 20 patients (66.7%) underwent single-level, 9 (30.0%) two-level and 1 (3.3%) three-level augmentation ($\chi^2 = 18.20$; $p < 0.001$).

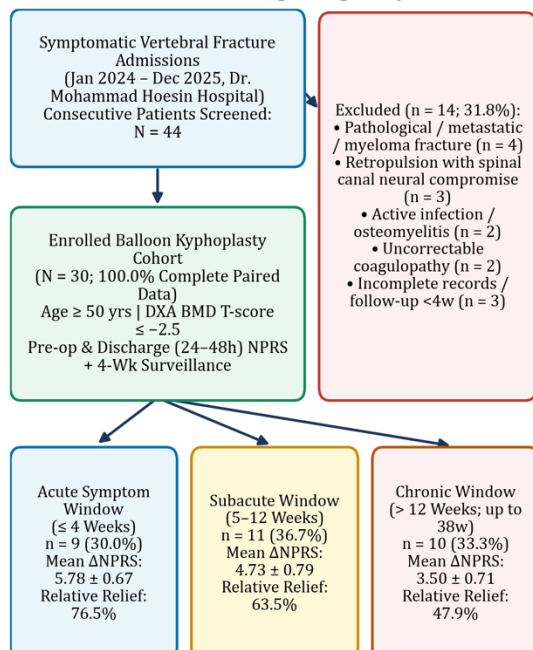
Table 1. Patient demographics, baseline clinical and radiological characteristics, and perioperative NPRS outcomes (N = 30).

Variable	Mean $\pm$ SD or n (%)	Range	95% CI	Median [IQR]	Normality / test†
Age (years)	67.2 ± 7.39	54–82	64.44 to 69.96	67.00 [61.00–73.00]	SW $W = 0.968$; $p = 0.485$
Sex				Female-to-male ratio 4.0:1.0	Binomial $p = 0.001^*$
Female	24 (80.0)	—	62.7% to 90.5%	—	
Male	6 (20.0)	—	9.5% to 37.3%	—	
BMD T-score (DXA)	-3.29 ± 0.64	-4.6 to -2.5	-3.53 to -3.05	-3.25 [-3.80 to -2.80]	SW $W = 0.942$; $p = 0.103$
Kyphotic angle ($^\circ$)	19.85 ± 7.71	8.5–34.2	16.97 to 22.73	19.40 [13.80–25.60]	SW $W = 0.959$; $p = 0.292$
Duration of complaints (weeks)	11.57 ± 9.68	2–38	7.96 to 15.18	8.50 [4.00–16.75]	SW $W = 0.864$; $p = 0.001^*$
Acute (≤ 4 weeks), n (%)	9 (30.0)	2–4	—	—	
Subacute (5–12 weeks), n (%)	11 (36.7)	5–12	—	—	
Chronic (> 12 weeks), n (%)	10 (33.3)	14–38	—	—	
Number of vertebral levels	1.37 ± 0.56	1–3	1.16 to 1.57	1.00 [1.00–2.00]	$\chi^2(2) = 18.20$; $p < 0.001^*$
Single level, n (%)	20 (66.7)	—	—	—	
Two levels, n (%)	9 (30.0)	—	—	—	
Three levels, n (%)	1 (3.3)	—	—	—	
Preoperative NPRS (0–10)	7.43 ± 0.77	6–9	7.14 to 7.72	7.50 [7.00–8.00]	SW $W = 0.918$; $p = 0.024^*$
Postoperative NPRS (discharge)	2.80 ± 0.81	1–5	2.50 to 3.10	3.00 [2.00–3.00]	SW $W = 0.912$; $p = 0.017^*$
Absolute pain reduction ($\Delta NPRS$)	4.63 ± 1.16	2–7	4.20 to 5.06	4.50 [4.00–5.50]	Paired $t = 21.86$; Wilcoxon $Z = -4.804$; both $p < 0.001^*$; Cohen's $d_z = 3.99$
Relative pain reduction (%)	62.3	28.6–87.5	—	—	
Any relief ≥ 2 points (MCID), n (%)	30 (100.0)	—	—	—	
Responders $\geq 50\%$ relief, n (%)	26 (86.7)	—	—	—	
Responders $\geq 60\%$ relief, n (%)	20 (66.7)	—	—	—	
$\Delta NPRS$ by duration of complaints					One-way ANOVA $F(2,27) = 23.41$; $p < 0.001^*$
Acute (≤ 4 weeks)	5.78 ± 0.67	—	—	6.00 [5.00–6.00]	
Subacute (5–12 weeks)	4.73 ± 0.79	—	—	5.00 [4.00–5.00]	

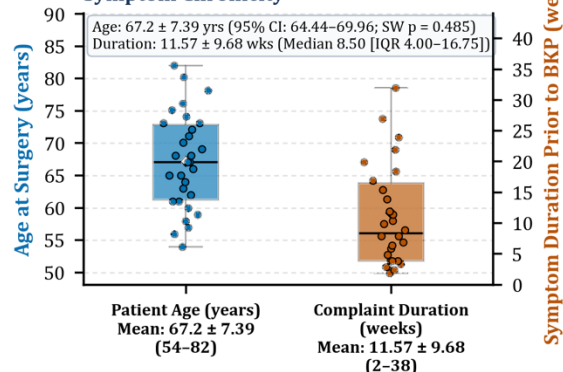
Variable	Mean ± SD or n (%)	Range	95% CI	Median [IQR]	Normality / test†
Chronic (> 12 weeks)	3.50 ± 0.71	—	—	3.50 [3.00–4.00]	

Notes: Continuous variables are mean ± SD, range, 95% CI and median [IQR, 25th–75th percentile]; categorical variables are n (%). †Normality was assessed with the Shapiro–Wilk test (SW W); the preoperative-to-postoperative change (Δ NPRS = preoperative – postoperative NPRS) was tested with the paired t test and the Wilcoxon signed-rank test (Z), with the paired effect size (Cohen's d_z). Abbreviations: ANOVA, analysis of variance; BMD, bone mineral density; CI, confidence interval; DXA, dual-energy X-ray absorptiometry; IQR, interquartile range; MCID, minimal clinically important difference; NPRS, Numerical Pain Rating Scale; SD, standard deviation. * $p < 0.05$.

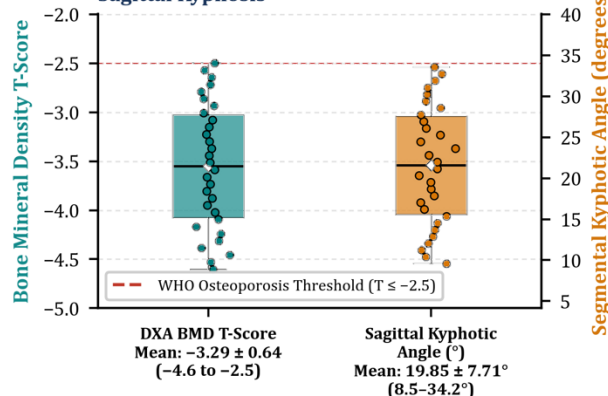
A. STROBE Cohort Screening & Eligibility Architecture



B. Baseline Distribution of Patient Age & Symptom Chronicity



C. Baseline Osteoporotic Severity (DXA) & Sagittal Kyphosis



D. Sex Predominance & Vertebral Fracture Multiplicity

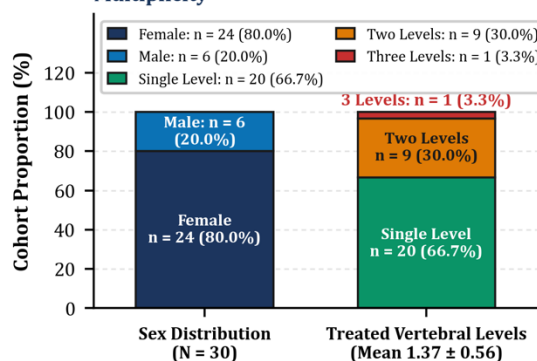


Figure 1. STROBE patient-selection flow and baseline clinical and radiological characteristics of the OVCF cohort treated with balloon kyphoplasty (N = 30). (A) Screening flow from 44 consecutive admissions to 30 enrolled patients stratified by symptom acuity. (B) Distribution of age (67.2 ± 7.39 years; range 54–82) and duration of complaints (11.57 ± 9.68 weeks; range 2–38). (C) DXA BMD T-score (-3.29 ± 0.64 ; range -4.6 to -2.5) and segmental kyphotic angle ($19.85 \pm 7.71^\circ$). (D) Sex distribution (female 80.0%, $n = 24$) and number of treated vertebral levels (single 66.7%, two 30.0%, three 3.3%). Abbreviations: BKP, balloon kyphoplasty; BMD, bone mineral density; CI, confidence interval; DXA, dual-energy X-ray absorptiometry; IQR, interquartile range; NPRS, Numerical Pain Rating Scale; OVCF, osteoporotic vertebral compression fracture; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology; SW, Shapiro–Wilk; WHO, World Health Organization.

Primary outcome and responder rates

Balloon kyphoplasty was followed by a rapid, statistically significant reduction in axial pain between the preoperative assessment and discharge at 24 to 48 hours (Table 1; Figure 2). Across the cohort (N = 30), mean NPRS decreased from 7.43 ± 0.77 points (range 6–9; 95% CI 7.14–7.72; median 7.50 [IQR 7.00–8.00]) before surgery to 2.80 ± 0.81 points at discharge (range 1–5; 95% CI 2.50–3.10; median 3.00 [IQR 2.00–3.00]). This corresponded to a mean absolute reduction of 4.63 ± 1.16 points on the 0–10 NPRS (range 2–7 points; 95% CI 4.20–5.06; median 4.50 [IQR 4.00–5.50]), or a 62.3% relative reduction

from baseline (paired $t = 21.86$, $p < 0.001$; Wilcoxon signed-rank $Z = -4.804$, $p < 0.001$). The paired effect size was large (Cohen's $d_z = 3.99$). All 30 patients (100.0%) achieved a reduction of at least 2.0 NPRS points, 26 (86.7%) a relative reduction of at least 50% and 20 (66.7%) a relative reduction of at least 60% before discharge. Pain reduction was smaller the longer the symptoms had lasted (Figure 2C; one-way ANOVA $F(2, 27) = 23.41$; $p < 0.001$): 5.78 ± 0.67 points (76.5% relative relief) for the nine acute cases (≤ 4 weeks), 4.73 ± 0.79 points (63.5%) for the 11 subacute cases (5–12 weeks), and 3.50 ± 0.71 points (47.9%) for the ten chronic cases (> 12 weeks).

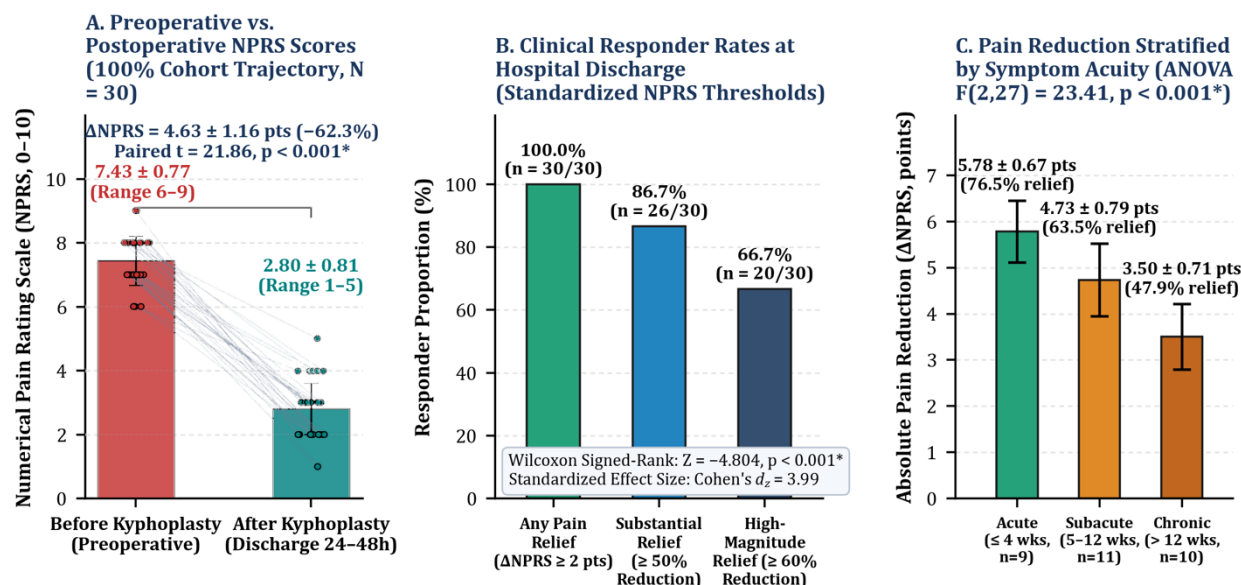


Figure 2. Preoperative and postoperative Numerical Pain Rating Scale (NPRS) scores and responder rates after balloon kyphoplasty (N = 30). (A) Individual trajectories showing a reduction from a preoperative mean NPRS of 7.43 ± 0.77 to a discharge mean of 2.80 ± 0.81 (mean absolute reduction 4.63 ± 1.16 points; 62.3% relative reduction; $p < 0.001$). (B) Proportion of patients achieving the minimal clinically important difference (≥ 2 points; 100.0%), $\geq 50\%$ pain reduction (86.7%; n = 26) and $\geq 60\%$ pain reduction (66.7%; n = 20). (C) Absolute pain reduction by symptom duration: acute (≤ 4 weeks; 5.78 ± 0.67 points), subacute (5–12 weeks; 4.73 ± 0.79 points) and chronic (> 12 weeks; 3.50 ± 0.71 points) ($p < 0.001$). Error bars show SD. Abbreviations: ANOVA, analysis of variance; SD, standard deviation.

Bivariate associations

In bivariate analysis of the unadjusted linear and monotonic relationships between the seven candidate variables and ΔNPRS, six variables were significantly associated with pain reduction (Table 2; Figure 3). Duration of complaints showed the strongest association: a large inverse correlation with pain reduction (Pearson $r = -0.747$; 95% CI -0.872 to -0.529 ; $r^2 = 55.8\%$; $p < 0.001$; Spearman $r_s = -0.762$; $p < 0.001$), indicating that a shorter symptom duration before balloon kyphoplasty was associated with greater pain reduction. Preoperative sagittal kyphotic angle showed the second strongest association, a moderate inverse correlation (Pearson $r = -0.499$; 95% CI -0.728 to -0.170 ; $r^2 = 24.9\%$; $p = 0.005$); patients with less severe kyphosis achieved larger absolute NPRS reductions than those with advanced collapse. Age showed a moderate negative correlation (Pearson $r = -0.481$; 95% CI -0.716 to -0.147 ; $r^2 = 23.1\%$; $p = 0.007$), indicating that younger age was associated with greater pain reduction.

The number of treated levels was negatively correlated with pain reduction (Spearman $r_s = -0.421$; 95% CI -0.678 to -0.071 ; $r^2 = 17.7\%$; $p = 0.021$); single-level procedures yielded greater reductions (4.95 ± 1.05 points) than two-level (4.11 ± 1.17 points) or three-level procedures (3.00 points). Sex showed a positive point-biserial correlation with pain reduction ($r_{pb} = 0.415$; 95% CI 0.064 to 0.674; $r^2 = 17.2\%$; $p = 0.023$), reflecting a greater unadjusted reduction in women (4.88 ± 1.08 points) than in men (3.67 ± 1.03 points). Preoperative T-score correlated positively with pain reduction (Pearson $r = 0.365$; 95% CI 0.006 to 0.641; $r^2 = 13.3\%$; $p = 0.047$): higher (less negative) T-scores, representing less severe bone loss, were associated with greater relief. Baseline NPRS was not significantly correlated with the absolute pain reduction (Pearson $r = 0.244$; 95% CI -0.129 to 0.556; $r^2 = 6.0\%$; $p = 0.194$).

Table 2. Bivariate correlations between candidate prognostic variables and postoperative pain reduction (ΔNPRS; N = 30).

Candidate variable	Correlation	Coefficient	95% CI	r^2	p value	Direction and multivariable entry
Duration of complaints (weeks)	Pearson r (Spearman r_s)	$r = -0.747^*$ ($r_s = -0.762^*$)	-0.872 to -0.529	55.8%	$< 0.001^*$	Shorter duration → greater ΔNPRS (entered)
Kyphotic angle (°)	Pearson r	$r = -0.499^*$	-0.728 to -0.170	24.9%	0.005*	Smaller kyphotic angle → greater ΔNPRS (entered)
Age (years)	Pearson r	$r = -0.481^*$	-0.716 to -0.147	23.1%	0.007*	Younger age → greater ΔNPRS (entered)
Number of vertebral levels	Spearman r_s	$r_s = -0.421^*$	-0.678 to -0.071	17.7%	0.021*	Single-level fracture → greater ΔNPRS (entered)
Sex (female = 1, male = 0)	Point-biserial r_{pb}	$r_{pb} = 0.415^*$	0.064 to 0.674	17.2%	0.023*	Female sex → greater ΔNPRS (entered)
BMD T-score (DXA)	Pearson r	$r = 0.365^*$	0.006 to 0.641	13.3%	0.047*	Higher (less severe) T-score → greater ΔNPRS (entered)
Preoperative NPRS score	Pearson r	$r = 0.244$	-0.129 to 0.556	6.0%	0.194	No significant linear association (not entered; $p = 0.144$ in the full-covariate model)

Notes: Bivariate associations with ΔNPRS were assessed with Pearson correlation (r) for continuous variables, Spearman rank correlation (r_s) for the ordinal number of levels (and as a non-parametric check for the skewed symptom duration), and point-biserial correlation (r_{pb}) for sex. Variables entered into the stepwise model are marked "entered". Abbreviations: BMD, bone mineral density; CI, confidence interval; DXA, dual-energy X-ray absorptiometry; NPRS, Numerical Pain Rating Scale. * $p < 0.05$ (two-tailed).

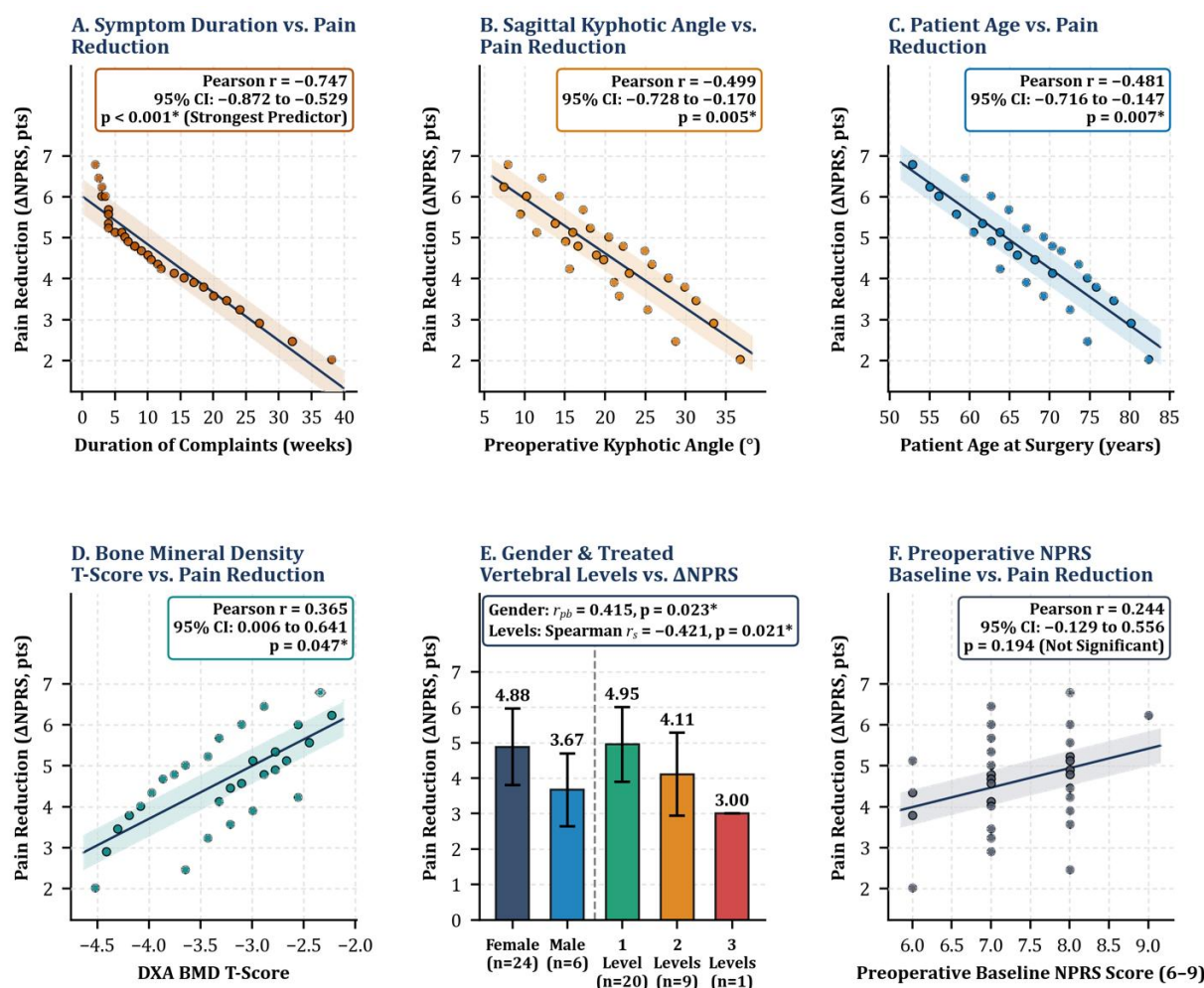


Figure 3. Bivariate associations between the seven candidate prognostic variables and postoperative pain reduction (Δ NPRS; $N = 30$). (A) Duration of complaints ($r = -0.747$; $p < 0.001$). (B) Preoperative sagittal kyphotic angle ($r = -0.499$; $p = 0.005$). (C) Age at surgery ($r = -0.481$; $p = 0.007$). (D) DXA BMD T-score ($r = 0.365$; $p = 0.047$). (E) Sex ($r_{pb} = 0.415$; $p = 0.023$) and number of treated vertebral levels ($r_s = -0.421$; $p = 0.021$); error bars show SD. (F) Preoperative NPRS score ($r = 0.244$; $p = 0.194$; not statistically significant). Lines and shaded bands show the fitted linear regression and its 95% confidence band. Abbreviations: BMD, bone mineral density; CI, confidence interval; DXA, dual-energy X-ray absorptiometry; NPRS, Numerical Pain Rating Scale; SD, standard deviation.

Multivariable regression and collinearity diagnostics

Six variables passed the bivariate screen (duration of complaints, kyphotic angle, age, number of treated levels, sex and T-score) and were offered to the stepwise multivariable linear regression (Table 3; Figure 4). Only duration of complaints and age stayed in the final model. Duration had the larger effect on pain reduction ($\beta = -1.881$; SE = 0.279; $t = -6.738$; 95% CI -2.452 to -1.310 ; $p < 0.001$), followed by age ($\beta = -0.428$; SE = 0.197; $t = -2.173$; 95% CI -0.831 to -0.025 ; $p = 0.039$), with an intercept of $\beta_0 = 16.841$ (SE = 3.521; $t = 4.784$; 95% CI 9.638 to 24.044 ; $p < 0.001$). The model was highly significant ($F(2, 27) = 35.579$; $p < 0.001$), with $R^2 = 0.723$, adjusted $R^2 = 0.702$ and a large effect size (Cohen's $f^2 = 2.61$). Symptom duration and age together accounted for 72.3% of the variance in postoperative pain reduction (adjusted $R^2 = 0.702$). In the full-covariate model (Figure 4A), sex ($\beta = 0.023$; $p = 0.841$), T-score ($\beta = 0.076$; $p = 0.574$), kyphotic angle ($\beta = -0.170$; $p = 0.139$), number of levels ($\beta = -0.112$; $p = 0.284$) and preoperative NPRS ($\beta = 0.188$; $p = 0.144$) were not independently significant after adjustment for symptom duration and age. All VIFs were well below 2.5 (1.18 for both duration and age in the final model, and 1.15 to 1.42 for the seven covariates in the full model; Figure 4B), indicating no important multicollinearity.

Comparison of bivariate and multivariable results

Comparison of the unadjusted bivariate correlations (Table 2) with the multivariable estimates (Table 3) shows why four variables that were significant in bivariate testing, namely kyphotic angle ($r = -0.499$; $p = 0.005$), number of treated levels ($r_s = -0.421$; $p = 0.021$), sex ($r_{pb} = 0.415$; $p = 0.023$) and T-score ($r = 0.365$; $p = 0.047$), were not retained in stepwise selection. In this cohort, patients presenting after more than 12 weeks also had more advanced segmental kyphosis (mean $24.8 \pm 6.9^\circ$ vs $15.1 \pm 5.8^\circ$ in acute fractures of ≤ 4 weeks), lower T-scores (-3.62 ± 0.58 vs -2.94 ± 0.52) and a higher prevalence of multilevel fractures (50.0% vs 11.1%). Similarly, the six men presented at an older mean age and with a longer mean symptom duration (16.8 ± 10.4 weeks) than the 24 women (10.3 ± 9.2 weeks). The unadjusted associations of greater kyphosis, multilevel involvement, lower T-score and male sex with smaller pain reduction were therefore attenuated after adjustment, consistent with their correlation with longer symptom duration and older age (mediation was not tested). After adjustment for duration of complaints ($\beta = -1.881$; $p < 0.001$) and age ($\beta = -0.428$; $p = 0.039$), the coefficients for kyphotic angle ($\beta = -0.170$; $p = 0.139$), T-score ($\beta = 0.076$; $p = 0.574$), number of levels ($\beta = -0.112$; $p = 0.284$) and sex ($\beta = 0.023$; $p = 0.841$) were not significantly different from zero, suggesting that time to augmentation and age were the main correlates of early postoperative pain reduction.

Table 3. Stepwise multivariable linear regression model and full-covariate collinearity check for postoperative pain reduction (N = 30).

Model variable	Coefficient (β)	SE	t	p value	95% CI	VIF
Final stepwise model						
Constant (intercept)	16.841*	3.521	4.784	< 0.001*	9.638 to 24.044	—
Duration of complaints (weeks)	-1.881*	0.279	-6.738	< 0.001*	-2.452 to -1.310	1.18
Age (years)	-0.428*	0.197	-2.173	0.039*	-0.831 to -0.025	1.18
Excluded covariates (full-covariate model)						
Preoperative NPRS	0.188	0.125	1.504	0.144	-0.068 to 0.444	1.15
Kyphotic angle (°)	-0.170	0.111	-1.532	0.139	-0.399 to 0.059	1.42
BMD T-score	0.076	0.133	0.571	0.574	-0.198 to 0.350	1.31
Sex (female vs male)	0.023	0.114	0.202	0.841	-0.210 to 0.256	1.24
Number of vertebral levels	-0.112	0.102	-1.098	0.284	-0.321 to 0.097	1.29

Notes: Final model $R^2 = 0.723$; adjusted $R^2 = 0.702$; $F(2, 27) = 35.579$; $p < 0.001$; Cohen's $f^2 = 2.61$. Duration of complaints and age together accounted for 72.3% of the variance in postoperative pain reduction (adjusted $R^2 = 0.702$). The unstandardized slopes used for Table 5 are -0.0813 NPRS points per week of symptom duration and -0.0428 points per year of age (-0.428 points per decade); the corresponding equation passes through the sample means (Δ NPRS 4.63 at a mean duration of 11.57 weeks and a mean age of 67.2 years). All VIFs were ≤ 1.42 , indicating no important multicollinearity. Abbreviations: BMD, bone mineral density; CI, confidence interval; NPRS, Numerical Pain Rating Scale; SE, standard error; VIF, variance inflation factor. * $p < 0.05$.

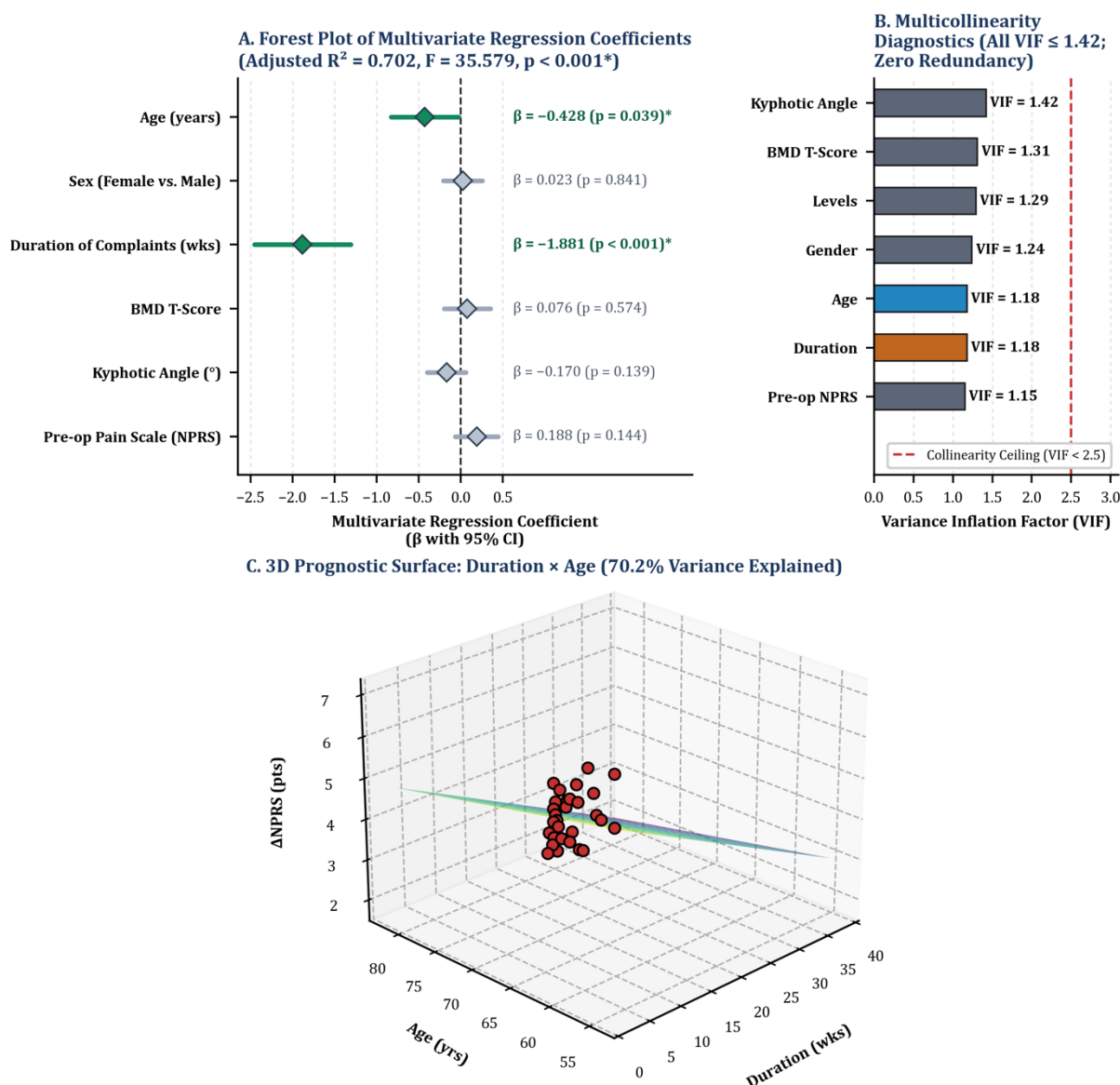


Figure 4. Stepwise multivariable linear regression, multicollinearity diagnostics and three-dimensional response surface (N = 30). (A) Forest plot of regression coefficients (β with 95% confidence intervals) identifying duration of complaints ($\beta = -1.881$; $p < 0.001$) and age ($\beta = -0.428$; $p = 0.039$) as independent predictors of pain reduction (adjusted $R^2 = 0.702$; $F = 35.579$; $p < 0.001$); sex ($p = 0.841$), BMD T-score ($p = 0.574$), kyphotic angle ($p = 0.139$) and preoperative pain score ($p = 0.144$) were not independently significant. (B) Variance inflation factors (all ≤ 1.42). (C) Three-dimensional response surface illustrating the joint (additive) effect of symptom duration and age on postoperative Δ NPRS. Abbreviations: BMD, bone mineral density; CI, confidence interval; NPRS, Numerical Pain Rating Scale; VIF, variance inflation factor.

Complications and prediction matrix

Perioperative adverse events were monitored from intraoperative fluoroscopy through discharge and the 4-week outpatient visit (Table 4; Figure 5B). Twenty-eight of the 30 patients (93.3%; 95% CI 78.7%–98.2%) had an uneventful recovery without radiographic or clinical complications. Asymptomatic cement leakage occurred in 2 patients (6.7%; 95% CI 1.8%–21.3%) and was detected on routine postoperative radiographs as minor paravertebral or epidural-margin extravasation without radicular irritation, spinal cord compression or neurological deficit; neither patient required revision surgery or prolonged hospitalization. No patient (0/30; 95% CI 0.0%–11.4%) developed symptomatic cement leakage, adjacent-level fracture, pulmonary cement embolism,

neurological deficit or surgical site infection during the 4-week follow-up.

To translate the regression findings into a bedside reference for preoperative counseling, expected pain reductions were tabulated for combinations of complaint duration (2, 8, 16 and 24 weeks) and age (55, 65 and 75 years) (Table 5; Figure 5A). Predicted reductions decreased with longer duration and older age (a linear model makes this gradient monotonic by construction), from 5.93 points (79.8% relief; expected discharge NPRS 1.50) at 2 weeks and 55 years to 3.29 points (44.3% relief; discharge NPRS 4.14) at 24 weeks and 75 years; at 65 years, predicted reductions ranged from 5.50 points (74.0%) at 2 weeks to 3.71 points (49.9%) at 24 weeks.

Table 4. Perioperative and 4-week postoperative complications after balloon kyphoplasty (N = 30).

Complication	n (%)	Wilson 95% CI	Detection method and site	Clinical manifestation and management
Cement leakage (asymptomatic)	2 (6.7)	1.8% to 21.3%	Postoperative fluoroscopy and radiographs (paravertebral; minor epidural margin)	Asymptomatic; no neurological deficit; observation only
Adjacent-level vertebral fracture	0 (0.0)	0.0% to 11.4%	Serial clinical and 4-week radiographic surveillance	None observed; routine anti-osteoporotic treatment maintained
Pulmonary cement embolism	0 (0.0)	0.0% to 11.4%	Perioperative cardiopulmonary and oxygen saturation monitoring	None observed
Neurological deficit or radiculopathy	0 (0.0)	0.0% to 11.4%	Serial postoperative motor and sensory examinations	None observed
Surgical site infection or spondylodiscitis	0 (0.0)	0.0% to 11.4%	Wound inspection and clinical follow-up through 4 weeks	None observed
Uneventful, complication-free course	28 (93.3)	78.7% to 98.2%	Complete 4-week postoperative review (N = 30)	Rapid mobilization and discharge within 24–48 hours

Notes: Complications are counts and percentages of the 30 patients with Wilson score 95% confidence intervals (CI). No symptomatic cement extravasation, neurological compromise, thromboembolic events or deep infections occurred during the index hospitalization or the 4-week follow-up.

Table 5. Predicted postoperative pain reduction (Δ NPRS) by symptom duration and age (N = 30).

Symptom duration before BKP	Age 55 years: predicted Δ NPRS [discharge NPRS]	Age 65 years: predicted Δ NPRS [discharge NPRS]	Age 75 years: predicted Δ NPRS [discharge NPRS]	Expected response tier and suggested management (not tested in this study)
2 weeks (acute phase)	5.93* (79.8% relief) [1.50]	5.50* (74.0% relief) [1.93]	5.07* (68.2% relief) [2.36]	Tier 1 (optimal early-responder window): standalone BKP expected to give rapid, large pain relief
8 weeks (subacute phase)	5.44* (73.2% relief) [1.99]	5.01* (67.4% relief) [2.42]	4.59* (61.8% relief) [2.84]	Tier 2 (subacute transition window): BKP plus targeted thoracolumbar fascial analgesia
16 weeks (early chronic phase)	4.79* (64.5% relief) [2.64]	4.36* (58.7% relief) [3.07]	3.94* (53.0% relief) [3.49]	Tier 3A (moderately attenuated window): preoperative expectation counseling plus multimodal rehabilitation
24 weeks (established chronic phase)	4.14* (55.7% relief) [3.29]	3.71* (49.9% relief) [3.72]	3.29* (44.3% relief) [4.14]	Tier 3B (chronic sensitized window): BKP stabilization plus central pain modulation

Notes: Predicted reductions (NPRS points) and expected relative relief (%) were calculated from the regression equation Δ NPRS = $8.447 - 0.0813 \times \text{duration (weeks)} - 0.0428 \times \text{age (years)}$, which passes through the sample means (Δ NPRS 4.63 ± 1.16 points; duration 11.57 weeks; age 67.2 years; adjusted $R^2 = 0.702$; $F = 35.579$; $p < 0.001$). Bracketed values are expected discharge NPRS scores relative to the cohort mean preoperative NPRS of 7.43 points. *All predictions exceed the 2.0-point minimal clinically important difference. Abbreviations: BKP, balloon kyphoplasty; NPRS, Numerical Pain Rating Scale.

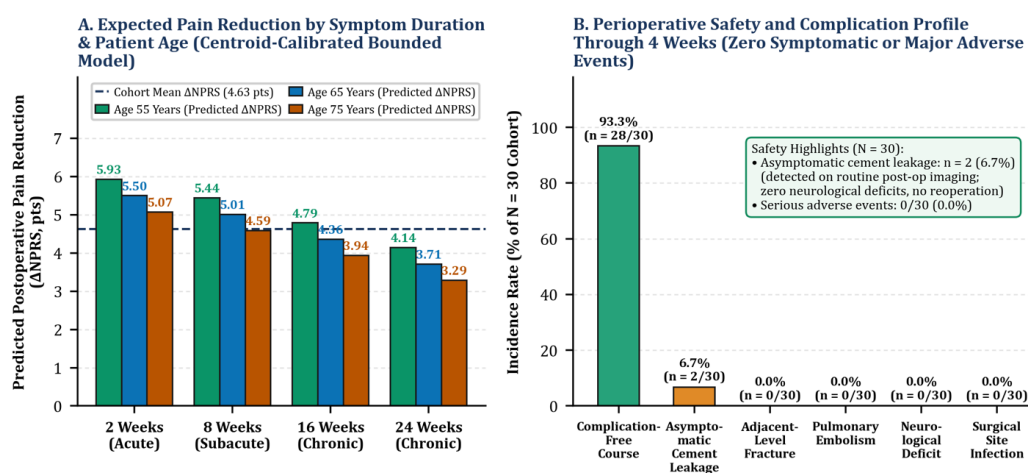


Figure 5. Predicted pain reduction by symptom duration and age, and 4-week postoperative complications (N = 30). (A) Predicted postoperative pain reduction (Δ NPRS) at symptom durations of 2, 8, 16 and 24 weeks for patients aged 55, 65 and 75 years, ranging from 5.93 points (79.8% relief) at 2 weeks in 55-year-old patients to 3.29 points (44.3% relief) at 24 weeks in 75-year-old patients (adjusted $R^2 = 0.702$; $p < 0.001$). (B) Postoperative safety: 93.3% ($n = 28$) of patients were complication-free, 6.7% ($n = 2$) had asymptomatic cement leakage, and no adjacent-level fracture, pulmonary embolism, neurological deficit or surgical site infection occurred. Abbreviation: NPRS, Numerical Pain Rating Scale.

4. Discussion

At our Indonesian referral center, mean NPRS fell by 62.3% (4.63 ± 1.16 points; $p < 0.001$) within 24 to 48 hours of balloon kyphoplasty for symptomatic OVCFs. Two patients had asymptomatic cement leaks (6.7%), and none had a neurological or cardiopulmonary complication. Two variables were independently associated with the size of the reduction in the multivariable model: how long the symptoms had lasted before surgery ($\beta = -1.881$; $p < 0.001$) and the patient's age ($\beta = -0.428$; $p = 0.039$). Together they explained 72.3% of the variance in pain reduction (adjusted $R^2 = 0.702$; $F = 35.579$; $p < 0.001$), which suggests that both the timing of the procedure and age shape the early relief obtained from vertebral augmentation.³²

The overall magnitude of early pain relief in this cohort (mean NPRS reduction from 7.43 ± 0.77 to 2.80 ± 0.81 ; Δ NPRS = 4.63 points) is consistent with randomized trials and recent meta-analyses.^{12,15,16,66} In syntheses and meta-analyses of vertebral augmentation outcomes by Nguyen et al. and Encalada et al., balloon kyphoplasty produced a rapid 4.0-to-4.8-point reduction on the 0–10 pain scale in the early postoperative period and outperformed non-surgical care.^{12,18} The 2025 systematic review and GRADE meta-analysis by Encalada et al. (nine studies, one of which was retrospective with prospectively collected data; 1,062 patients) reported that balloon kyphoplasty had its largest effect over conservative management within the first postoperative month (mean difference -2.32 points; $p < 0.001$), with sustained superiority through 12 months.¹² The immediate post-procedure reduction in our cohort also parallels the 2025 retrospective study of day-surgery versus inpatient percutaneous kyphoplasty by An et al. ($N = 299$), in which VAS scores in the day-surgery group ($n = 133$) declined from 5.56 ± 1.11 before surgery to 1.86 ± 0.78 on postoperative day 1, and 84.7% of the 157 day-surgery patients completed the 24-hour ambulatory pathway.³⁵ The rapid onset of analgesia within 24 to 48 hours suggests that the main analgesic mechanism of balloon kyphoplasty is immediate mechanical stabilization of load-bearing trabecular microfractures, possibly with thermal and chemical injury to intraosseous nerve endings during exothermic PMMA polymerization.³²

The main clinical finding of our study is that duration of complaints before treatment was the strongest predictor of postoperative pain reduction, both in bivariate analysis ($r = -0.747$; $p < 0.001$) and in stepwise multivariable regression ($\beta = -1.881$; $p < 0.001$).^{32,33} Patients treated in the acute phase (≤ 4 weeks after symptom onset) achieved a mean NPRS reduction of 5.78 ± 0.67 points (76.5% relief), compared with 4.73 ± 0.79 points (63.5%) for subacute fractures (5–12 weeks) and 3.50 ± 0.71 points (47.9%) for chronic fractures (> 12 weeks). This gradient agrees with the 2026 retrospective cohort study by Wu et al. ($N = 111$), in which percutaneous vertebroplasty with a curved-angle needle performed within 2 weeks of symptom onset yielded a significantly larger VAS reduction (7.19 ± 0.68 points, from 8.12 ± 0.46 to 0.93 ± 0.52) and greater kyphotic angle correction (-5.65° vs -0.76° ; $p < 0.001$) than delayed surgery (> 2 weeks; VAS reduction 4.71 ± 0.61 points).³² Wei and colleagues (2025; $N = 120$) found that vertebroplasty performed 7 to 14 days after the fracture restored more anterior vertebral height and caused less immobilization-related morbidity than surgery at 15 to 28 days; in their series, however, timing did not alter postoperative VAS or ODI scores.³³

Three interconnected mechanisms may explain why prolonged symptom duration attenuates the analgesic response to balloon kyphoplasty, as summarized in the conceptual

framework in Figure 6.^{32,33} First, during the acute inflammatory phase of an OVCF (described as weeks 1 to 2 by Wu et al.;³² up to 4 weeks in this study), the fracture line remains mobile and unbridged by mineralized callus; pain is predominantly peripheral and mechanonociceptive, driven by micromotion of fragmented cancellous trabeculae and periosteal stretch during axial loading.^{32,33} Balloon inflation in this compliant window readily elevates the depressed endplate, and interdigitating PMMA locks the mobile fragments, abolishing this peripheral pain generator.^{19,32} Second, when fractures remain unstabilized beyond 8 to 12 weeks, fibrous organization, sclerotic remodeling or avascular osteonecrosis with a fibrocartilaginous membrane (intravertebral vacuum cleft) develops within the vertebral body.^{22,26,30} In the meta-analysis by Chen et al. (13 studies; 4,876 patients), fracture nonunion (OR = 4.67; $p < 0.001$) and intravertebral vacuum clefts (OR = 3.52; $p < 0.001$) were risk factors for residual pain, and Wang et al. (11 studies; 3,290 patients) reported an OR of 2.33 for vacuum clefts; such lesions prevent uniform interdigitation of PMMA with the surrounding trabeculae and may leave interfacial micromotion and residual pain after augmentation.^{22,23} Third, persistent nociceptive input from an unstabilized fracture can trigger dorsal horn central sensitization, characterized by wind-up of wide-dynamic-range neurons, NMDA receptor phosphorylation and neuroglial activation,^{46,47} together with secondary overload of the posterior thoracolumbar fascia and paraspinal muscles.^{39,44} Once pain processing has centralized and paravertebral myofascial edema is established, mechanical stabilization of the anterior vertebral body alone may not fully reverse the pain syndrome.^{44,46}

The relationship between preoperative sagittal kyphotic angle (mean $19.85 \pm 7.71^\circ$; range 8.5 – 34.2°) and early postoperative analgesia is also relevant.^{15,19,53} In bivariate analysis, kyphotic angle showed a moderate negative correlation with pain reduction ($r = -0.499$; $p = 0.005$): patients with more severe wedge deformity had smaller NPRS reductions. This might appear paradoxical, because balloon kyphoplasty is designed to restore vertebral height and reduce focal kyphosis.^{15,19} Three mechanisms may account for it.^{28,39,53} First, severe segmental kyphosis ($\geq 20^\circ$) in osteoporotic spines often reflects progressive anterior trabecular creep, cortical comminution and subacute-to-chronic collapse over many weeks.^{32,33} In the scoring system developed by Yang et al., segmental kyphosis $\geq 20^\circ$ and age ≥ 60 years were among the predictors of residual back pain after kyphoplasty,^{22,67} possibly because severe wedging accompanies advanced structural damage and delayed presentation. Second, in a cohort of 62 balloon kyphoplasty patients followed for 20.7 months, Teraguchi et al. (2024) found that, although kyphoplasty markedly reduced local fracture pain (NRS from 8.4 to 0.4 immediately after the procedure), preoperative global sagittal imbalance (sagittal vertical axis [SVA] ≥ 5.0 cm, OR = 4.76; pelvic incidence minus lumbar lordosis [PI-LL] $\geq 20^\circ$, OR = 3.78) was associated with poor health-related quality of life (EQ-5D-5L < 0.65) after the procedure.⁵³ Patients with severe kyphosis have a greater burden of global sagittal malalignment and compensatory pelvic retroversion, which may continue to cause fatigue pain in the thoracolumbar extensor muscles after the index vertebra is cemented.^{39,53} Third, severe anterior wedge collapse stretches the posterior ligamentous complex and thoracolumbar fascia across adjacent segments. When symptom duration and age were controlled for in our multivariable model, the independent effect of kyphotic angle decreased to $\beta = -0.170$ ($p = 0.139$), consistent with confounding by symptom duration.

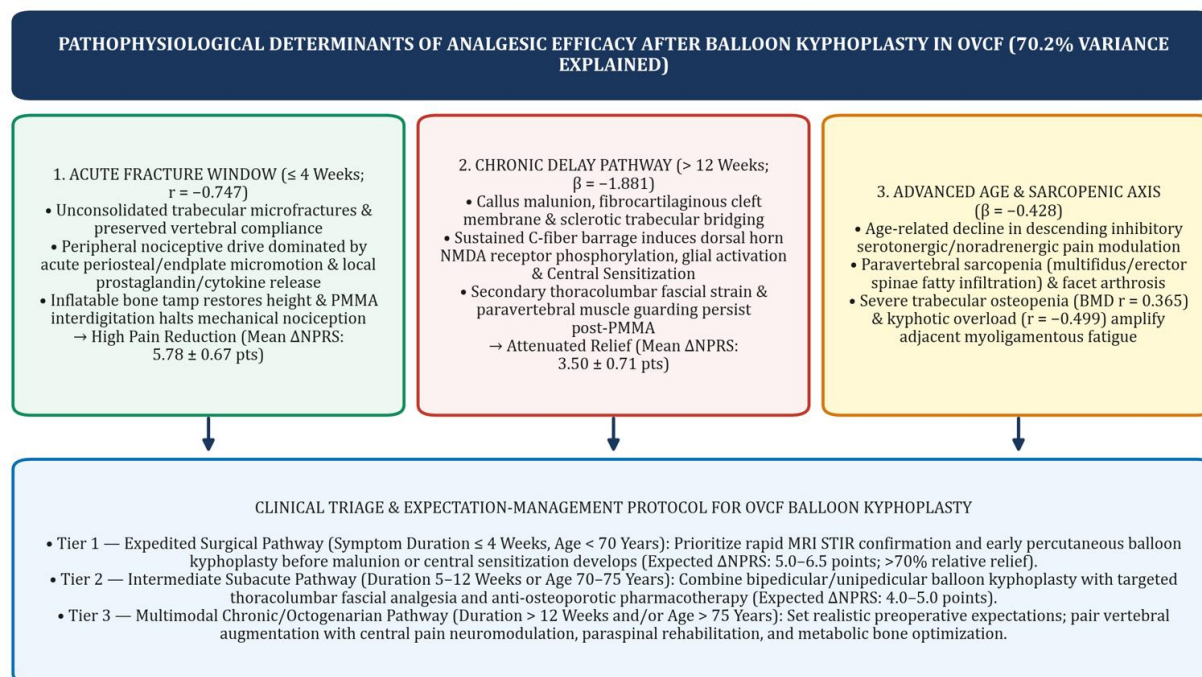


Figure 6. Proposed conceptual framework linking symptom duration and age with postoperative analgesia after balloon kypheoplasty for osteoporotic vertebral compression fractures. Early intervention (≤ 4 weeks) may halt acute periosteal and endplate micromotion before trabecular malunion and dorsal horn central sensitization develop, whereas advanced age may reduce descending endogenous pain inhibition and add paravertebral sarcopenic fatigue. The mechanisms shown were not measured in this study, and the triage tiers are hypotheses for prospective testing. Abbreviations: BMD, bone mineral density; MRI, magnetic resonance imaging; NMDA, N-methyl-D-aspartate; NPRS, Numerical Pain Rating Scale; OVCF, osteoporotic vertebral compression fracture; PMMA, polymethylmethacrylate; STIR, short tau inversion recovery.

The behavior of DXA T-scores (cohort mean -3.29 ± 0.64 ; range -4.6 to -2.5) across the analyses is also instructive.^{22,23,27} In bivariate analysis, T-score correlated positively with pain reduction ($r = 0.365$; $p = 0.047$): patients with less severe osteoporosis (T-scores closer to -2.5) achieved greater early relief than those with profound bone depletion (T-scores approaching -4.6). This unadjusted association is consistent with the meta-analysis by Chen et al. (pooled OR = 5.56; 95% CI 3.83–8.09; $p < 0.001$; six studies) and that by Wang et al. (pooled mean difference 0.39 T-score units; $p < 0.01$; ten studies), both of which identified low preoperative BMD as a risk factor for residual back pain after vertebral augmentation.^{22,23} In finite-element models, rigid PMMA bone cement (Young's modulus about 2,000–3,000 MPa) injected into a vertebral body with very low trabecular density (T-score ≤ -3.5 ; Young's modulus < 50 MPa) creates a marked stiffness mismatch at the cement-trabecular interface.⁶⁸ Under axial loading, the uncemented osteopenic trabeculae surrounding the rigid PMMA bolus may undergo microscopic crushing and stress-shielding micromotion, which can perpetuate low-grade nociceptor firing.²⁷ Nevertheless, in our stepwise model, T-score was not independently significant ($\beta = 0.076$; $p = 0.574$) after adjustment for age and complaint duration. Li et al. (2021, N = 268) suggested that low bone density is a risk factor for long-term rather than short-term (1-month) residual back pain after vertebroplasty,³⁰ and in Yu et al. (2023, N = 236), BMD was not a significant predictor of residual pain after kypheoplasty.²⁶

The role of fracture multiplicity also merits comment: 66.7% (n = 20) of our cohort underwent single-level balloon kypheoplasty, 30.0% (n = 9) two-level and 3.3% (n = 1) three-level augmentation (mean 1.37 ± 0.56 levels).^{23,25} In bivariate rank analysis, treating more levels was associated with smaller pain reduction (Spearman $r_s = -0.421$; $p = 0.021$), with mean reductions of 4.95 ± 1.05 points for single-level procedures, 4.11

± 1.17 points for two-level procedures and 3.00 points in the three-level case. Multisegment OVCFs impose cumulative soft-tissue and biomechanical trauma: each additional fractured vertebra adds paravertebral muscle spasm, widens the zone of posterior thoracolumbar fascial edema and requires additional transpedicular trocar trajectories through the lumbodorsal fascia and paraspinal muscles.^{23,25,44} In the meta-analysis by Wang et al., posterior thoracolumbar fascial injury (pooled OR = 3.94; 95% CI 3.10–5.00; $p < 0.01$) and facet joint capsule violation during trocar insertion (pooled OR = 7.71; 95% CI 3.50–17.00; $p < 0.01$) were strong predictors of early postoperative back pain.²³ In our cohort, patients with two- and three-level fractures were also older and presented after longer symptom intervals; accordingly, the partial effect of the number of levels was attenuated in multivariable regression ($\beta = -0.112$; $p = 0.284$). In multilevel procedures, precise fluoroscopic entry trajectories that avoid facet capsule violation and adjunctive thoracolumbar interfascial plane anesthetic infiltration may reduce iatrogenic myofascial pain, although these measures were not evaluated in this study.^{23,35}

Sex differences were also examined.^{1,25} The 80.0% female composition of our cohort (24 women vs 6 men) mirrors international OVCF cohorts, such as those of Feng et al. (2025; 82.2% female), Rong et al. (2025; 78.6%), Li et al. (2021; 80.2%) and Teraguchi et al. (2024; 79.0%), and reflects the accelerated loss of cancellous bone after menopause due to estrogen deficiency and increased RANKL-mediated osteoclastogenesis.^{2,3,28,30,39,53} In bivariate analysis, female sex was positively correlated with pain reduction (point-biserial $r_{pb} = 0.415$; $p = 0.023$), with a mean reduction of 4.88 ± 1.08 points in women versus 3.67 ± 1.03 points in men. Although sex-specific differences in endogenous opioid systems, central pain modulation and health-seeking behavior have been described in the musculoskeletal pain literature,^{69,70} sex was not associated

with pain reduction after adjustment for complaint duration and age ($\beta = 0.023$; $t = 0.202$; $p = 0.841$). Men in our cohort tended to present later, when symptoms had become chronic (mean 16.8 vs 10.3 weeks in women), and at an older mean age. This is consistent with the 2025 meta-analysis of 9,703 patients in 26 studies by Li et al., which found almost identical pooled prevalences of residual back pain in men (15.9%; 95% CI 12.5%–19.2%) and women (16.1%; 95% CI 13.1%–19.1%), suggesting that sex itself does not limit the efficacy of vertebral augmentation.²⁵

Our finding that baseline pain intensity (mean NPRS 7.43 ± 0.77 ; range 6–9) did not correlate significantly with absolute pain reduction ($r = 0.244$; $p = 0.194$; multivariable $\beta = 0.188$; $p = 0.144$) is relevant to perioperative triage.²⁶ In some surgical populations, higher baseline pain scores mathematically allow larger absolute decreases because of regression to the mean. However, patients with symptomatic OVCs selected for balloon kyphoplasty all present with moderate-to-severe pain within a narrow range (NPRS 6–9).³² Within this band, for example, a patient with an NPRS score of 9 and a 24-week chronic malunited fracture may fall only to an NPRS score of 5 or 6 (Δ NPRS = 3–4 points) because of established central sensitization and myofascial deconditioning, whereas a patient with an NPRS score of 7 at 2 weeks after fracture may fall to 1 or 2 (Δ NPRS = 5–6 points) after immediate mechanical stabilization.^{32,33} Therefore, preoperative pain severity alone does not distinguish rapid mechanical responders from chronic partial responders; the duration of pain before cement augmentation appears to be the more informative prognostic factor.^{32,33}

From a health-system perspective in Indonesia, the finding that longer symptom duration was associated with smaller early pain reduction has practical implications.^{32,33,35} Under the tiered referral system of the Indonesian National Health Insurance (Jaminan Kesehatan Nasional; BPJS Kesehatan), patients are first managed at primary health centers (Puskesmas) and are referred to secondary and then tertiary hospitals,³⁷ so older patients with acute low back pain after a minor fall are often treated with oral analgesics and plain radiographs, without early MRI or timely referral to a spine surgeon. Because early osteoporotic compression fractures may show subtle or no anterior wedging on initial radiographs while showing marrow edema on T2-weighted STIR MRI, they are often missed on primary radiographic examination,⁷¹ and diagnosis may be delayed by 8 to 24 weeks, until progressive collapse and kyphotic deformity become obvious on radiographs. In our model, predicted reductions fell from 5.07–5.93 NPRS points at 2 weeks to 3.29–4.79 points at 16–24 weeks (Table 5; ages 55–75 years), and observed relative relief was 76.5% in acute and 47.9% in chronic presentations. These findings support fast-track geriatric fragility-fracture pathways in Indonesian referral hospitals. Specifically, expedited DXA screening and sagittal T1-weighted and T2-weighted STIR spinal MRI within 1 to 2 weeks of symptom onset may be considered for patients aged ≥ 50 years with acute focal thoracolumbar percussion tenderness and risk factors for osteoporosis, so that balloon kyphoplasty can be offered within the ≤ 4 -week window.⁷¹

Age was the second independent negative predictor of pain reduction in our model ($r = -0.481$; $p = 0.007$ in bivariate analysis; $\beta = -0.428$; $p = 0.039$ in multivariable regression): younger patients within the 54-to-82-year range achieved greater reductions than patients in their seventies and eighties.²⁷ This finding is consistent with reports linking age-related muscle degeneration to residual pain after augmentation, although none of these studies found age itself to

be an independent predictor of residual pain.^{27,39,48,49,52} In recent cohorts, fatty infiltration of $\geq 49.8\%$ of the multifidus and erector spinae muscles (Feng et al., 2025; $N = 213$) and sarcopenia defined by the skeletal muscle mass index (Li et al., 2025; $N = 231$; OR = 2.15; $p = 0.031$) were associated with residual back pain after percutaneous kyphoplasty, the latter approximately doubling its incidence.^{27,39} Even after the fractured vertebral body is stabilized with PMMA, older patients with sarcopenic paravertebral extensor muscles may be unable to maintain sagittal balance without muscle fatigue, causing persistent myofascial and facet-mediated pain.^{27,48,49} Aging is also accompanied by a decline in endogenous descending pain-inhibitory pathways from the periaqueductal gray and rostral ventromedial medulla, degenerative spondylosis at adjacent segments and greater vulnerability to central pain amplification.^{50,51} Importantly, the prediction matrix (Table 5; Figure 5A) indicates that patients aged 75 years may still obtain clinically meaningful benefit from balloon kyphoplasty, with predicted reductions of 5.07 NPRS points when treated at 2 weeks and 3.29 points at 24 weeks; advanced age alone therefore need not preclude surgery, but calls for realistic preoperative counseling and multimodal rehabilitation.^{12,39}

Taken together, kyphotic angle, the number of treated levels, female sex and T-score were each significant on their own but dropped out of the stepwise model.^{22–25,28} Unadjusted, greater kyphosis, multilevel fractures and lower T-scores went with smaller pain reductions, in line with pooled data linking low BMD (OR = 5.56; $p < 0.001$; Chen et al.) and poor kyphosis correction (Wang et al.) to residual pain after augmentation.^{22,23} In our patients, though, these features were concentrated among those who came late (> 12 weeks) and were older, so their effects shrank once duration and age entered the model. The absent correlation between baseline NPRS and pain reduction likewise reflects the narrow band of severe pain (NPRS 6–9) needed for surgical indication: patients starting at NPRS 8–9 can reach low postoperative scores, just as those starting at 6–7 can, provided they are treated early.²⁶

The perioperative safety profile in this series, with 6.7% (2/30) asymptomatic cement leakage and no symptomatic extravasation, neurological deficit, pulmonary embolism, infection or early adjacent-level fracture, compares favorably with published data.^{15,60,65} In the 2025 meta-analysis of 3,392 augmented vertebrae by Wu et al., the pooled cement leakage rate was 18% (95% CI 12%–24%) after kyphoplasty and 36% after vertebroplasty,⁶⁰ and the 2025 meta-analysis of 16 randomized trials ($N = 1,738$) by You et al. found higher odds of leakage with vertebroplasty than with kyphoplasty (OR = 1.92; $p < 0.0001$).¹⁵ Rose et al. likewise reported fewer leaks after kyphoplasty than after vertebroplasty (28.9% vs 39.3%).⁷² Preserving cortical wall continuity, creating a balloon cavity and injecting high-viscosity PMMA under continuous biplanar fluoroscopic control mitigate the risk of extravasation: cortical disruption, low-viscosity cement and larger cement volumes increase the risk of leakage, whereas high-viscosity cement reduces it.^{61,65} The low asymptomatic leakage rate in our series may reflect strict adherence to the inclusion criteria (exclusion of burst fractures with posterior wall retropulsion), careful transpedicular cannula placement and controlled low-pressure delivery of doughy-phase PMMA; leakage detected on plain radiographs is, however, likely to be underestimated.

Several methodological limitations should be considered. First, the retrospective single-center design and the sample of 30 patients limit statistical power to detect small-to-moderate independent effects of secondary covariates (such as kyphotic

angle and T-score) and preclude causal inference in the absence of a non-operative control group. Stepwise selection from up to seven candidates in 30 patients also carries a risk of overfitting, and the three patients excluded for incomplete records or loss to follow-up may have biased the sample. Second, although all patients completed at least 4 weeks of clinical and radiological follow-up for complications, the primary pain endpoint was assessed at discharge (24 to 48 hours), so long-term pain trajectories, functional disability indices (such as the Oswestry Disability Index [ODI] or EQ-5D-5L) and late adjacent-level refracture rates at 6 to 24 months could not be captured.^{53,55,73} Third, MRI biomarkers recently linked to residual post-kyphoplasty pain, such as the percentage of paravertebral muscle fatty infiltration, thoracolumbar fascial edema on STIR sequences, the global SVA and standardized depression and catastrophizing scales, were not routinely recorded in our retrospective records.^{25,26,39,53} Prospective multicenter Indonesian studies with larger cohorts, 12-to-24-month follow-up, quantitative MRI phenotyping of muscle and fascia, and randomized comparisons of timing are needed to validate these prognostic thresholds.

Comparison with major clinical series from Europe, North America, China and Japan places our Southeast Asian cohort in context.^{12,28,53} The multinational FREE trial (Wardlaw et al.) enrolled patients with acute fractures and back pain that had started within the previous 3 months,^{66,74} and the meta-analysis by Encalada et al. focused on fractures of less than 3 months' duration (mean approximately 4 to 6 weeks), which maximized the proportion of acute nociceptive responders.¹² By contrast, in our tertiary referral setting at Dr. Mohammad Hoesin General Hospital, one-third of patients (33.3%; $n = 10$) presented more than 12 weeks after symptom onset (up to 38 weeks), reflecting socioeconomic, geographic and referral delays across South Sumatra. This wide spread of symptom chronicity (2 to 38 weeks; SD = 9.68 weeks) provided statistical leverage to detect the steep linear decline in analgesic response over time ($r = -0.747$; $p < 0.001$). Two single-center Chinese studies of residual back pain (VAS ≥ 4 at 1 month²⁸ and VAS ≥ 3.5 at 12 months²⁶) found fracture-to-surgery time non-significant (as a continuous variable in one and as < 6 vs ≥ 6 weeks in the other), whereas intravertebral vacuum clefts or posterior fascial edema remained significant in logistic regression. These lesions may themselves partly reflect delayed fracture stabilization and progressive collapse.^{32,33} When pain reduction is analyzed as a continuous endpoint (Δ NPRS) across a broad 2-to-38-week range, symptom duration was the strongest predictor in our cohort.

The interplay between mechanical stabilization and metabolic bone treatment also has implications for clinical practice in Indonesia and other developing health systems.^{54,73,75} Balloon kyphoplasty corrects local segmental mechanics at the fractured vertebra, but it does not arrest systemic osteoclastic bone turnover in the rest of the spine.^{73,75} In the 2026 study by Jin et al. ($N = 120$), adding alfacalcidol to percutaneous kyphoplasty with calcium and vitamin D supplementation improved postoperative BMD, suppressed serum β -isomerized C-terminal telopeptide (β -CTX) and yielded better 6- and 12-month pain and function scores,⁷⁵ and the 2026 risk-stratified cohort study by Zhu et al. (three cohorts; $N = 796$) evaluated the outcomes of vertebral augmentation according to metabolic and other risk factors.⁵⁴ Similarly, Yu et al. (2023) found that the absence of postoperative anti-osteoporotic treatment increased the odds of residual low back pain almost tenfold (OR = 9.63; $p < 0.01$), possibly because of ongoing trabecular microfractures in uncemented regions of the spine.²⁶

Combining our regression model (adjusted $R^2 = 0.702$) with published neurobiological and biomechanical evidence, we propose a three-tier triage and perioperative management scheme for OVCF patients considered for balloon kyphoplasty (Table 5; Figure 6); this scheme is a hypothesis for prospective testing rather than a validated algorithm.^{12,32,39,75} In Tier 1 (optimal early-responder window: symptom duration ≤ 4 weeks and age < 70 years), where the expected pain reduction is 5.0 to 5.9 NPRS points ($> 70\%$ relative relief), clinical pathways could prioritize rapid STIR MRI confirmation and early balloon kyphoplasty, before vertebral malunion or dorsal horn sensitization develops.^{32,43} In Tier 2 (subacute transition window: symptom duration 5–12 weeks or age 70–75 years; expected Δ NPRS 4.5 to 5.4 points), balloon kyphoplasty could be combined with targeted perioperative management of secondary thoracolumbar fascial strain and early physical therapy.^{39,44} In Tier 3 (chronic sensitized or octogenarian window: symptom duration > 12 weeks and/or age > 75 years; expected Δ NPRS 3.3 to 4.4 points), clinicians could provide transparent preoperative counseling, aligning patient expectations with a pain reduction of about 45%–55%, and integrate balloon kyphoplasty into a multimodal regimen including central pain modulation (e.g., gabapentinoids or duloxetine for centralized pain),^{76,77} targeted paraspinal muscle strengthening to counteract sarcopenic fatigue, and anti-osteoporotic pharmacotherapy.^{27,39,75}

5. Conclusion

In this retrospective cohort, balloon kyphoplasty for symptomatic OVCFs was followed by a mean pain reduction of 4.63 ± 1.16 NPRS points (62.3% relative relief; $p < 0.001$) within 24 to 48 hours of surgery, with a 6.7% rate of asymptomatic cement leakage and no serious neurological or cardiopulmonary complications. In stepwise multivariable linear regression, duration of complaints before treatment ($\beta = -1.881$; $p < 0.001$) and age ($\beta = -0.428$; $p = 0.039$) were independently associated with smaller early pain reduction ($R^2 = 0.723$; adjusted $R^2 = 0.702$; $F = 35.579$; $p < 0.001$). Patients treated in the acute fracture window (≤ 4 weeks) and at younger ages achieved the largest gains, whereas prolonged symptom duration and advanced age attenuated, but did not abolish, postoperative pain relief. These factors may help clinicians to expedite diagnostic MRI and surgical referral for acute OVCFs, set realistic preoperative expectations using the prediction model, which requires external validation, and plan multimodal analgesia, paraspinal rehabilitation and anti-osteoporotic treatment for older patients and those presenting with chronic fractures.

Prospective multicenter studies across Southeast Asian spine centers, with 12-to-24-month follow-up, validated functional disability instruments and quantitative MRI assessment of paravertebral sarcopenia and thoracolumbar fascial injury, are needed to refine individualized risk stratification in osteoporotic spine care.

6. Declarations

Ethics Approval and Consent to Participate

This study was reviewed and approved by the Institutional Health Research Ethics Committee of the Faculty of Medicine, Universitas Sriwijaya and Dr. Mohammad Hoesin General Hospital, Palembang, Indonesia (Reference No. 2023/201). All study procedures were conducted in accordance with the ethical principles of the Declaration of Helsinki and its later amendments. Written informed consent was obtained from all 30 participants before surgery.

Consent for Publication

Not applicable. No individually identifiable patient data, images or clinical details are reported.

Availability of Data and Materials

The anonymized analytical dataset supporting the findings of this study is available from the corresponding author upon reasonable request.

Artificial Intelligence Use Statement

None declared.

Author Contribution Statement

R.S.: Conceptualization, Investigation, Methodology, Data curation, Formal analysis, Writing – original draft, Project administration. R.L.: Supervision, Investigation, Validation, Writing – review & editing. D.H.H.: Methodology, Software, Formal analysis, Data curation, Writing – review & editing. All authors read and approved the final manuscript.

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Conflict of Interest / Competing Interests

The authors declare no financial or non-financial competing interests.

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