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The effectiveness of balloon kyphoplasty compared to conservative treatment for osteoporotic vertebral compression fractures: A systematic review and meta-analysis

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A R T I C L E I N F O

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Systematic review

A B S T R A C T

Background: Osteoporotic vertebral compression fractures (OVCFs) are a common and often debilitating condition that significantly impacts quality of life and healthcare costs. While conservative treatment is often pursued initially after fracture, some patients experience severe pain refractory to conservative treatment. In these cases, minimally invasive vertebral augmentation procedures like balloon kyphoplasty (BKP) offer an alternative, but the benefits of BKP compared to conservative treatment remain unclear.
Objectives: To evaluate the effectiveness of BKP versus conservative treatment for pain, quality of life, and function in patients with painful OVCFs.
Primary outcome: Pain improvement up to 12 months after BKP.
Secondary outcomes: Functional improvement, adverse events, and vertebral body height restoration.
Methods: This analysis included randomized controlled trials and prospective comparative studies in which at least 100 participants reported pain outcomes following BKP for OVCFs. The risk of bias was assessed using standard tools, and the certainty of the evidence was evaluated using the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach.
Results: BKP demonstrated superior pain reduction versus conservative treatment at 1 month (mean difference (MD): 2.32 [-3.65;-0.99], $P < 0.001$), 3 months (MD: 1.19 [-2.14; −0.24], $P = 0.014$), 6 months (MD: 1.34 [-2.65; −0.04], $P = 0.044$), and 12 months (MD: 1.11 [-1.96;-0.26], $P = 0.029$), with the largest effect observed at 1 month. Disability improvements were significant at 1 month (standardized mean difference (SMD): 1.08 [-1.67; −0.48], $P < 0.001$) and 3 months (SMD: 0.50 [-0.96; −0.04], $P = 0.032$), but not at 6 or 12 months. No significant differences were found in the risk for new vertebral compression fractures between both groups (odds ratio (OR): 1.36 [0.51; 3.64], $P = 0.54$). According to the GRADE system, moderate certainty evidence indicates that BKP provides superior pain relief compared to conservative treatment at all time points from 1 to 12 months.
Conclusion: BKP showed superior pain reduction compared to conservative treatment from 1 to 12 months and improved disability at 1 and 3 months, with moderate certainty evidence.

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1. Introduction

Osteoporotic vertebral compression fractures (OVCFs) represent a common complication of axial skeletal fragility affecting approximately 1.4 million people annually and impose a considerable economic burden attributed to an estimated annual cost of $13.8 billion [1,2].

For patients experiencing painful OVCFs, various conservative treatment options are often employed as first-line management. Pain control and osteoporosis pharmacotherapy, either alone or in combination with physical therapy, represent the most commonly recommended therapeutic approaches [3]. Yet, for many patients, conservative treatment results in insufficient pain relief, limiting function and decreasing quality of life. Conservative treatment may also carry significant risks, particularly gastrointestinal tract complications associated with the use of nonsteroidal anti-inflammatory drugs (NSAIDs) and the development of decubitus ulcers and muscle atrophy due to inactivity. Currently, evidence supporting optimal conservative treatment protocols for OVCFs remains limited [4].

Balloon kyphoplasty (BKP) has proven to be an effective treatment alternative for OVCFs in patients with significantly limiting pain or pain that is refractory to conservative management [5]. This minimally invasive procedure implements a percutaneous technique to introduce an inflatable balloon and inject cement, typically polymethylmethacrylate (PMMA), into the fractured vertebral body. The primary objectives are stabilizing the fracture, restoring mechanical function, and alleviating pain [6].

Several studies have suggested that BKP may offer superior pain relief and functional improvement over conservative treatment, with reduced mortality benefits [7]. However, previous systematic reviews comparing BKP to conservative treatment are dated, with most being over 5 years old, and have been limited by the number of included studies, small sample sizes, and analysis of long-term outcomes [8–13]. By including updated evidence, larger patient cohorts, and extended follow-up periods, this systematic review and meta-analysis aims to assess the effectiveness of BKP compared with conservative treatment in terms of pain, quality of life, and function in patients experiencing painful OVCFs.

2. Methods

2.1. Objectives

This systematic review aimed to define the effectiveness of BKP versus conservative treatment in patients with OVCFs.

2.2. Protocol and registration

This systematic review and meta-analysis followed established Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [14]. All team members reviewed the protocol to ensure accuracy and completeness. The review protocol was registered in the PROSPERO database [CRD42022310302].

2.3. Eligibility criteria

Population: Adults with acute/subacute OVCF.
Intervention: BKP.
Comparator: Conservative treatment (e.g., pharmacological management, bracing, physical therapy).

2.3.1. Outcomes

- Primary outcome: Pain improvement measured by Visual Analog Scale (VAS) or other validated pain rating scales
- Secondary outcomes:
  - o Functional improvement
  - o Adverse events
  - o Vertebral body height restoration

The analyses incorporated response rates for standardized pain and functional outcomes, applying instrument-specific minimal clinically important differences as thresholds [15,16]. The analyses focused on fractures with a duration of less than 3 months from onset to intervention, excluding chronic fractures. This definition of fracture chronicity supported comprehensive outcome analysis across different time points, addressing the critical aspect of patient selection timing in vertebral augmentation procedures.

2.3.2. Studies

Randomized controlled trials (RCTs) and prospective comparative studies involving at least 100 total participants reporting pain outcomes following BKP and conservative treatment for OVCFs were included. To capture the broadest relevant evidence base, studies utilizing any imaging-guided BKP technique and any established fracture classification system were included. Studies specifically examining vertebroplasty or cervical OVCFs were excluded.

The review was limited to studies from 2002 onwards, given that this period marked the initial FDA clearance and clinical implementation of BKP. Retrospective studies, prospective cohort studies (total $n < 100$), case reports, expert opinion, unpublished data, and studies not published in English were excluded. The review was restricted to studies with larger cohorts to focus on adequately powered studies, given that when enough such studies exist, including smaller or inadequately powered studies contributes little additional helpful information [17].

2.4. Search strategy

The search was conducted in English from January 1, 2002, to October 7, 2024, and included the following databases: Ovid MEDLINE (R), Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily, Ovid EMBASE, Ovid Cochrane Central Register of Controlled Trials, Ovid Cochrane Database of Systematic Reviews, and Scopus. The comprehensive search strategy involved multiple databases and a combination of controlled vocabulary and relevant keywords, designed and conducted by an experienced librarian with input from the study's principal investigator. The actual search strategy listing all the search terms used and how they were combined is available as supplementary material (Appendix 1).

2.5. Evidence review and data extraction

Evidence review and data extraction were conducted using Covidence (Covidence Systematic Review Software, Veritas Health Innovation, Melbourne, Australia; available at www.covidence.org), a screening and data extraction tool for conducting systematic reviews. The Covidence tool was used to identify and eliminate duplicates generated by the literature search. Two reviewers independently reviewed all abstracts generated to identify those that potentially met inclusion criteria. Subsequently, the same two authors independently reviewed all full-text articles to determine if, in fact, the studies met eligibility criteria. Discrepancies were discussed to achieve consensus. All authors participated in data extraction. Two authors were assigned to independently extract data from each of the included studies and discuss their assessments to achieve consensus. A third reviewer resolved any discrepancies. During data extraction, reference lists of included studies were reviewed to identify any potential articles that may have been missed by the literature search. None were identified. For reports corresponding to the same RCT, this review included data at all time points of interest, with studies cited based on the longest follow-up data, typically the last publication in a series.

2.6. Risk of bias

The risk of bias assessment was conducted in accordance with Cochrane guidelines. This review utilized the Cochrane Risk of Bias 2 (RoB 2) tool for RCTs. This instrument evaluates five domains: (1) bias due to the randomization process; (2) bias due to deviations from intended interventions; (3) bias due to missing outcome data; (4) bias due to outcome measurement; and (5) bias due to selective reporting [18]. For non-randomized studies, this study employed the Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I) tool, which assesses seven domains of potential bias [19]. Two independent reviewers evaluated each domain for all included studies, with discrepancies resolved by a third reviewer.

2.7. Grades of Recommendation, assessment, development, and evaluation (GRADE)

The Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach was used to evaluate outcomes in terms of inconsistency, indirectness, imprecision, publication bias, and risk of bias [20]. This method allows for a transparent, comprehensive assessment of the available evidence, considering the study methodology and sources of bias that could affect confidence in the estimated outcome. Initially, the quality of evidence was judged based on existing data and further assessed for weaknesses and strengths that could either downgrade or upgrade the rating. The effectiveness of BKP was evaluated based on published data, and the overall conclusions regarding the certainty of the evidence were drawn using the GRADE system. Disagreements among reviewers were resolved through consensus.

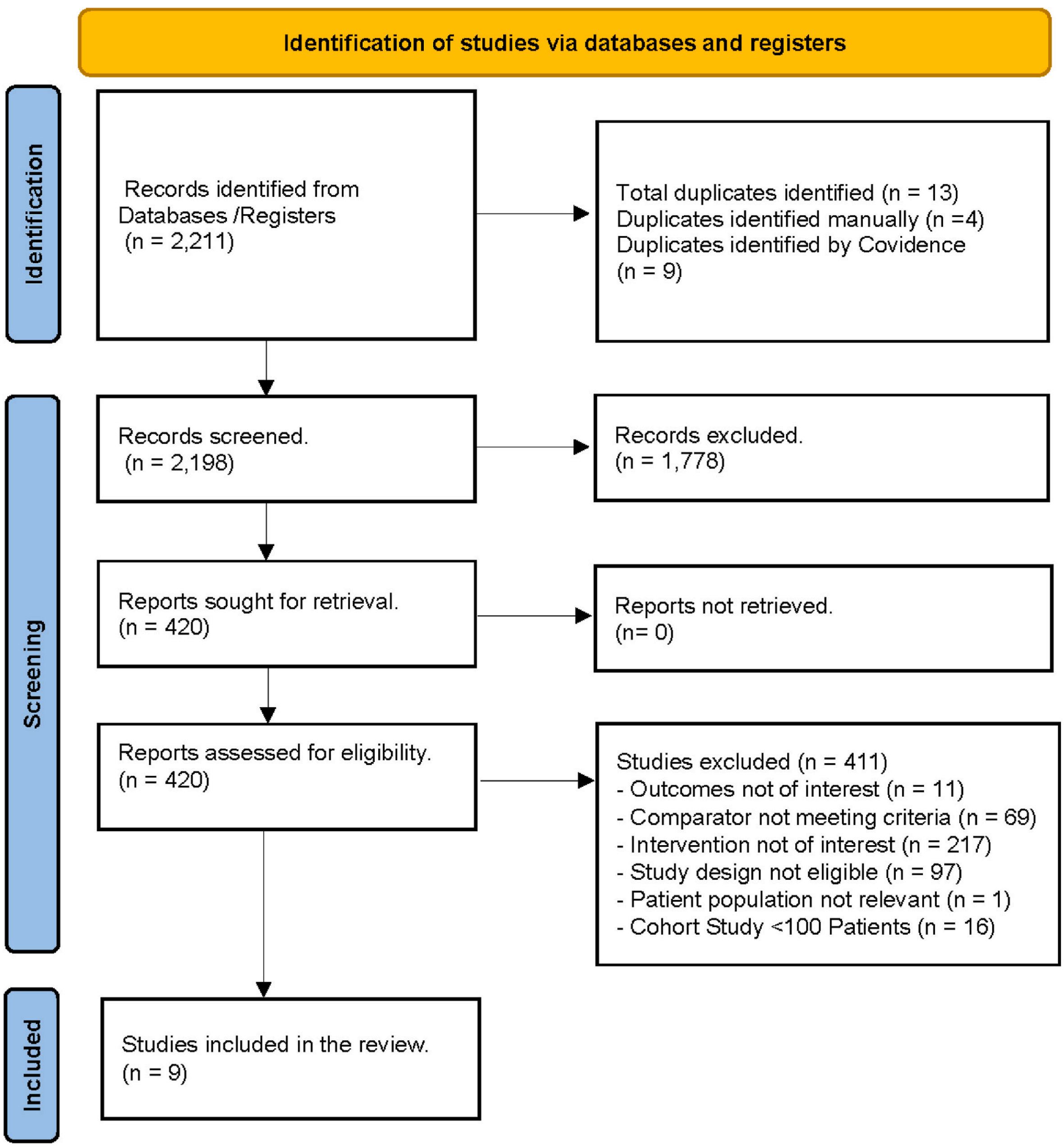

Fig. 1. Prisma flow chart.

2.8. Statistical analyses

Continuous data were analyzed using mean differences (MD) with 95 % confidence intervals (CI) for standardized outcomes (e.g., VAS) and standardized mean differences (SMDs) when similar outcomes were measured with different instruments (e.g., Disability questionnaires). If studies reported continuous data as a 95 % CI, the standard deviations (SDs) were calculated from standard errors (SEs) as described by Cochrane [21]. If data were reported as SEs, SDs were calculated. For dichotomous outcomes, the number of events was analyzed for each group using odds ratios (OR) and 95 % CI. Statistical heterogeneity was assessed using I^2. The random effects model was employed when high heterogeneity was found (I^2 >50 %). The value of $P < 0.05$ was considered to be statistically significant. R studio version R 4.3.2. was used for calculations.

3. Results

The search strategy yielded 2211 studies; after removing 13 duplicates, 2198 remained. After excluding 1778 studies, 420 underwent full-text review, and 411 were excluded for reasons detailed in Fig. 1. Nine studies remained for final analysis and data extraction, totaling 1062 participants (505 BKP, 557 conservative treatment) (see Table 1).

3.1. Description of studies

This systematic review identified six pragmatic RCTs. Three reports were part of the Fracture Reduction Evaluation (FREE) trial [22–24] and were funded by Medtronic. The remaining studies consisted of two prospective comparative nonrandomized trials [25,26] and one retrospective comparative study [27] that collected data prospectively and was deemed appropriate for this review. The included studies enrolled patients with vertebral fractures of varying acuity from 2 weeks to 3 months. Seven studies evaluated pain reduction, function, and disability improvement as their primary objective [22–24,26–29], while two additional studies explored these outcomes as secondary analyses [25,30]. Pain assessment was conducted using the VAS. Functional disability was measured through validated instruments, including the Oswestry Disability Index (ODI) and Roland Morris Disability Questionnaire (RMDQ). Additional functional outcomes were evaluated using the 36-item Short Form Survey (SF-36) and Barthel Index, while health-related quality of life was assessed using the EuroQol 5-dimension questionnaire (EQ-5D) (Table 1). None of the included studies reported responder rates for the outcomes of interest, nor did they provide data from which the responder rates could be calculated.

Table 1
Study characteristics.

	Inclusion Criteria			Participants								
Author/type of study	**Acuity**	**Pain Severity**	**Other**	**Total (n)**	**BKP/CT**	**Mean age (Female %) BKP/CT**	**BKP description**	CT description	Follow-up (months)	Scale of pain	Scale of function	Scale of quality of life
Pragmatic RCT												
FREE trial	<3 months	4/10	>15 % decrease of VB height	300	149/151	72.2 (77)/74.1 (77)	Bilateral, transpedicular/extrapedicular under fluoroscopy	Non-pharmacological medical therapies + bed rest, physical therapy + analgesia + osteoporosis therapy	24	VAS	SF-36/PCS RMDQ	EQ-5D
Liu (2019)	NR	NR	Elderly patients	116	58/58	65.34 (67)/65.78 (50)	Bilateral transpedicular under fluoroscopy	Analgesia + physical therapy + bed rest	NR	VAS	Barthel Index	NR
Li (2017)	2 h to 2 weeks	NR	≥65 years old, compression fractures confirmed by imaging	80	40/40	74.32 (25)/74.36 (35)	Unilateral transpedicular under fluoroscopy	Bed rest + physical therapy + vitamin D3 and calcium carbonate + osteoporosis therapy	6	VAS	ODI	NR
Jin (2018)	NR	NR	>60 years old, single-level fracture, linear black signal on STIR image	41	24/17	75.8 (75)/72.1 (71)	Unilateral transpedicular under fluoroscopy	Bed rest + back brace + analgesia + osteoporosis therapy	12	VAS	SF-36/PCS	NR
Lee (2012)	3 weeks	SBP	>50 years, LOF: ≤T8	259	91/168	76.8 (63.9)/66.2 (59)	Bilateral transpedicular under fluoroscopy	Analgesia + bed rest + back brace + walking aids	12	VAS	ODI	NR
Movrin (2012)	<6 weeks	>5/10	Kyphotic deformity >30°	107	46/61	67.8 (78.3)/73.8 (49)	Bilateral transpedicular under fluoroscopy	Analgesia + bed rest	12	VAS	NR	NR
Retrospective Analysis												
Ee (2015)	1 month	>5/10	Failure of CT after 1 month	363	97/62	75 (89.7)/76 (83.9)	NR	Oral analgesics + bed rest + back brace + physical therapy	BKP: 24 CT: 6	VAS	ODI SF-36	NR

Abbreviations: BKP, Balloon kyphoplasty; CT, Conservative treatment; DXA, Dual-energy X-ray absorptiometry; EQ-5D, EuroQol 5 dimension; LOF, Level of fracture; NR, Not reported; ODI, Oswestry Disability Index; PCS, physical component summary; RCT; Randomized control trial; SBP, Severe back pain; SF-36, Short Form 36; VAS: Visual Analog Scale; VB, Vertebral body.

3.2. Pain

This review found that BKP significantly reduced pain compared to conservative treatment. The greatest pain reduction was observed at 1 month (MD: 2.32 [−3.65; −0.99], P < 0.001, n = 917 from 6 studies), with sustained benefits at 3 months (MD: 1.19, 95 % CI [−2.14; −0.24], P = 0.0138, n = 603, 4 studies), 6 months (MD: 1.34, 95 % CI [−2.65; −0.04], P = 0.0435, n = 695, 4 studies), and 12 months (MD: 1.11, 95 % CI [−1.96; −0.26], P = 0.0108, n = 614, 4 studies). While substantial variation in pain reduction was observed across studies (I^2 = 98 %), the evidence consistently demonstrated BKP's superior pain relief throughout the follow-up period (see Fig. 2).

3.3. Function and quality of life

BKP showed varying effectiveness in improving disability scores, with the largest benefit at 1 month (SMD: 1.08 [−1.67; −0.48], P < 0.001, n = 605 from 3 studies), followed by significant improvement at 3 months (SMD: 0.50 [−0.96; −0.04], P = 0.032, n = 562 from 3 studies). Differences were not statistically significant at 6 months (SMD: 0.23 [−0.81; 0.35], P = 0.434, n = 477 from 2 studies) or 12 months (SMD: 0.21 [−0.47; 0.05], P = 0.114, n = 466 from 2 studies). While substantial variation in treatment effects was observed across studies (I^2 = 89.7 %), the overall evidence suggested BKP's superiority in disability improvement, particularly in early follow-up periods (see Fig. 3).

The limited data reported for function and quality of life among studies limited the analysis of estimated effects. Some studies measured fun ctional improvement using SF-36 questionnaires [22–24,27]. The FREE trial reported significant improvements in SF-36 physical component summary scores among the BKP group compared to conservative treatment from months 1–6 (P = 0.001) [22–24]. However, this difference did not persist at the 12-month follow-up (P = 0.0956). Ee et al. reported improvements in SF-36 scores at 1, 6, and 24 months following BKP [27]. These outcomes lacked comparison with conservative treatment. Jin et al. reported higher SF-36 scores with BKP versus conservative treatment at 1 year (78.1 ± 11.5 vs 64.5 ± 20.3; P = 0.02) [30]. One RCT measured function using the Barthel index and found significant improvement in scores in patients that underwent BKP

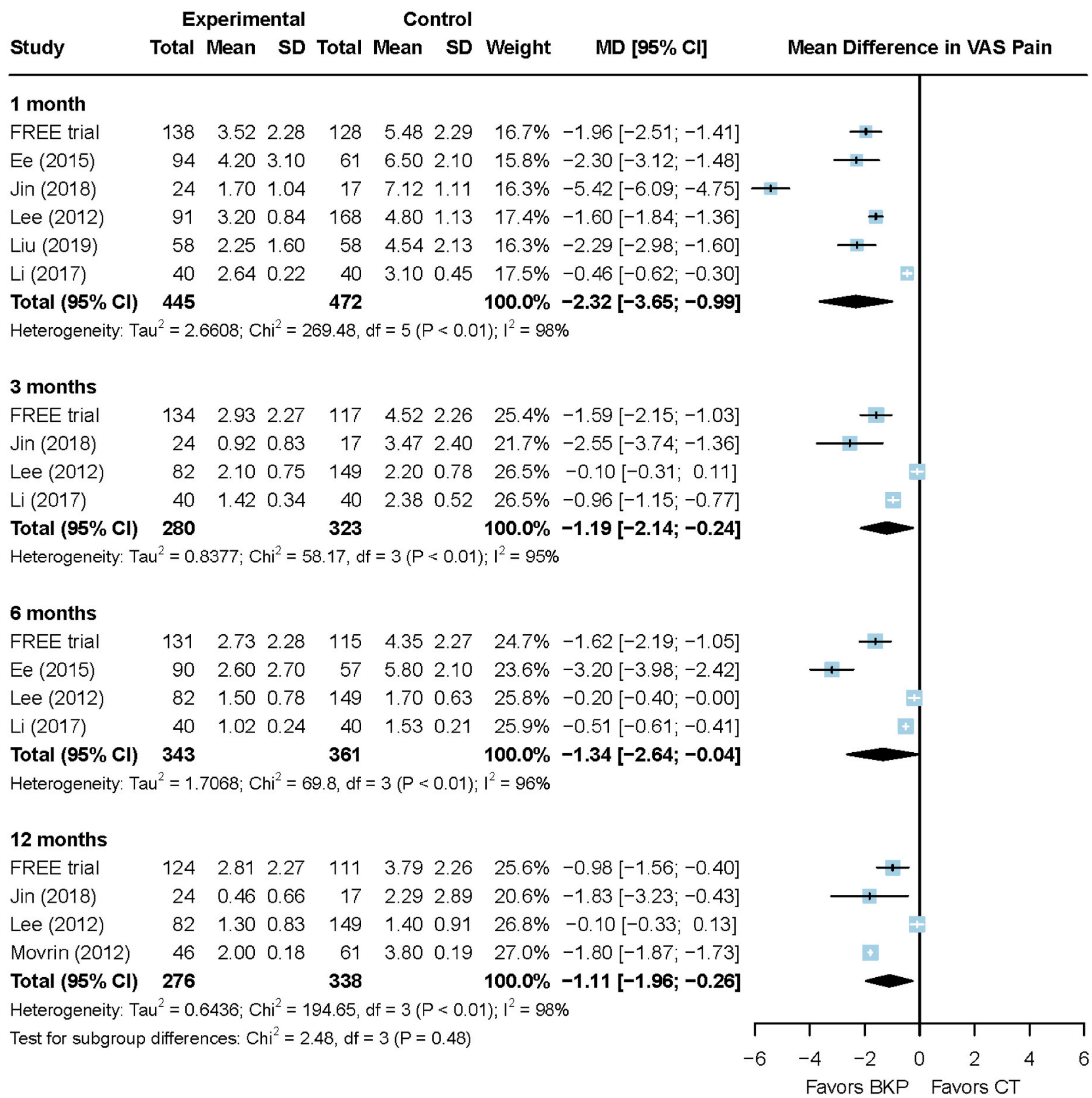

Fig. 2. Pain outcomes at follow-up time points through 12 months. SD, standard deviation; MD, mean difference; CI, confidence interval; VAS, visual analog scale; BKP, balloon kyphoplasty; CT, conservative treatment.

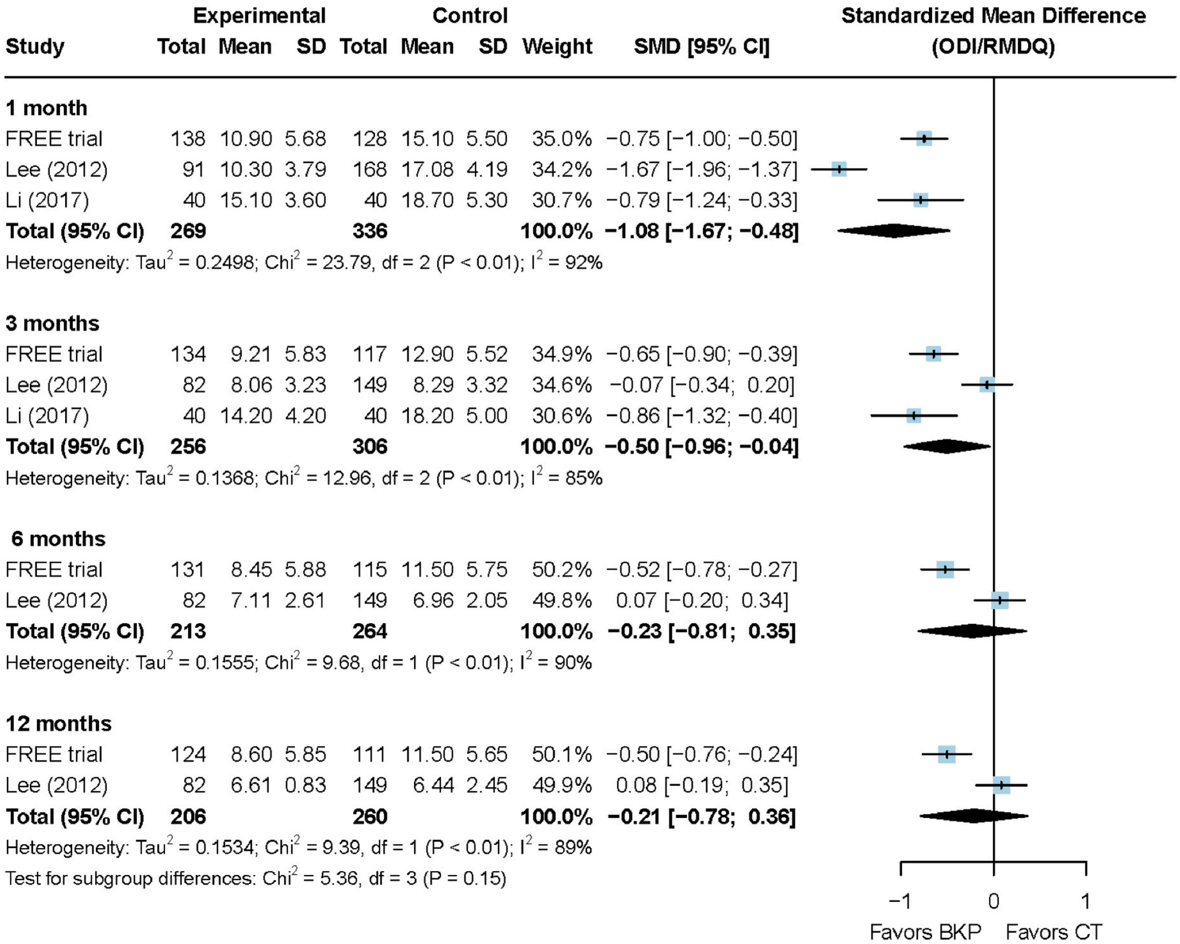

Fig. 3. Disability outcomes through 12 months. SD, standard deviation; SMD, standardized mean difference; CI, confidence interval; BKP, balloon kyphoplasty; CT, conservative treatment.

compared to conservative treatment at 12-month follow-up [28]. Quality of life was evaluated only by the FREE trial using the EQ-5D questionnaire, finding significant clinical and statistical differences in favor of BKP through all time points up to 24 months [22–24].

3.4. Adverse events

There were no significant differences in the risk of subsequent vertebral compression fractures between groups (OR: 1.36 [0.51; 3.64], P = 0.54, n = 743 from 4 studies) (Fig. 4). Cement extravasation varied across studies: FREE trial reported asymptomatic extravasation in 51/188 vertebrae (27 %) [22–24], Ee et al. reported asymptomatic extravasation in 11.3 % of cases [27], while Liu et al. (1/58, 1.7 %) [28] and Movrin et al. (4/46, 8.7 %) [25] reported extravasation events without specifying symptom status. Other adverse events, including wound site hematoma and infections, were reported at lower rates in the BKP group [22–24,27,28]. The reporting of adverse events in the conservative treatment group was inconsistent.

3.5. Vertebral body height restoration

Due to inconsistent data reporting of vertebral body height restoration across studies, a meta-analysis and GRADE assessment were not feasible. We have summarized relevant findings as reported in the studies meeting inclusion criteria. Vertebral body height restoration was consistently superior with BKP compared to conservative treatment across studies. Immediate postoperative benefits of BKP were substantial, with anterior vertebral body height increasing by 10.0 % and mid-

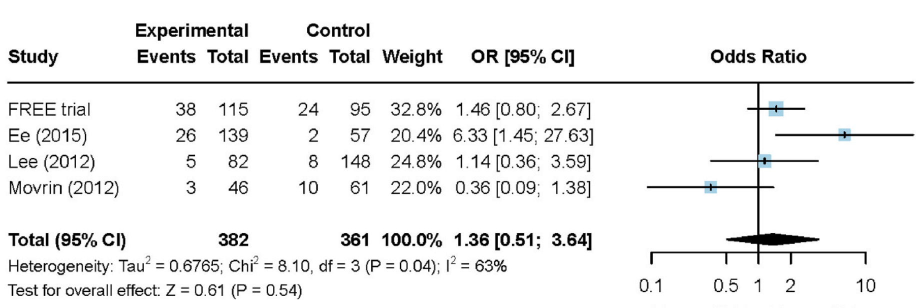

Fig. 4. Odds of new vertebral fractures. OR, odds ratio; CI, confidence interval; BKP, balloon kyphoplasty; CT, conservative treatment.

vertebral height improving by 8.3 % [24]. The observed improvements persisted at 24 months, with the BKP arm maintaining anterior and medial vertebral body height improvements of 6.7 % and 5.9 %, respectively, while the conservative treatment group showed minor improvement or deterioration [24]. The magnitude of vertebral body height restoration varied across studies but demonstrated a clear pattern of improvement. Jin et al. found anterior vertebral body height increased from approximately 55 %–76 % following BKP, with concurrent improvement in kyphosis angle from 16° to 7° [30]. Adding further evidence, Li et al. showed vertebral body height improvements from 9.8 mm to 14.2 mm 1-week post-procedure [29]. BKP sustained vertebral body height across long-term assessments. At 1 year, BKP-treated vertebrae showed minimal vertebral body height loss (compression rate deterioration 4.9 %) compared to vertebrae in those managed with conservative treatment (14.7 %) [25]. While the Ee et al. study reported more variable results with anterior vertebral body height restoration of 29 % [27], the overall pattern across studies suggests that BKP provides both immediate and sustained vertebral body height restoration superior to conservative treatment.

3.6. *Risk of bias*

3.6.1. *RoB - 2*

All RCTs in this review demonstrated a high risk of bias, with each study showing at least one critical limitation. The FREE trial maintained methodological rigor through its randomization process, but other specific sources of potential bias were present [22–24]. Although treatment-arm unblinding was inherent to the surgical intervention design, non-blinded assessment of patient-reported outcomes and differential attrition rates between conservative treatment (24 %) and BKP groups (17 %) raised concerns. Jin et al.'s study presented critical methodological limitations through inadequate reporting of the randomization process, unclear allocation concealment methods, substantial attrition (36 % lost to follow-up), and non-blinded outcome assessment [30]. Liu et al. and Li et al.'s studies exhibited limitations in outcome assessment blinding and data management, with additional concerns about insufficient documentation of missing data handling [28, 29]. Both studies lacked protocol pre-registration, raising concerns about selective reporting bias (Fig. 5).

3.6.2. *ROBINS-I*

The non-RCT studies showed a moderate to serious risk of bias. Ee et al.'s study presented methodological limitations through selection bias, as patient preferences and economic constraints determined conservative treatment allocation [27]. Additional concerns originated from differential follow-up rates between groups, non-blinded assessment of patient-reported outcomes, and insufficient adjustment for potential confounding variables. Lee et al.'s study revealed moderate risk through unclear adjustment methods for confounding factors [26]. Allocation based on symptoms after 3 weeks of conservative treatment and economic factors raised concerns for selection bias. Movrin et al.'s study raised serious methodological concerns due to uncontrolled confounding factors [25]. Specifically, significant baseline differences between groups in age, deformity severity, and pain scores remained unaddressed through statistical adjustment. The self-selection of participants into treatment groups presented further limitations. Non-blinded radiographic measurements and assessment of patient-reported outcomes could introduce reporting bias.

4. GRADE

Moderate certainty evidence showed that BKP provides better pain improvement at all time points (1, 3, 6, and 12 months). With the evidence available from RCTs and non-RCTs, the resulting body of evidence was initially assigned a "high" quality rating; however, the body of evidence was downgraded by one level due to the risk of bias. A proportion of the included studies had a high or unclear risk of bias in one or more domains that could potentially influence the results (e.g., lack of blinding of participants and personnel for subjective outcomes). Despite high heterogeneity across studies (I^2 statistic), the evidence was not downgraded as pooled analyses consistently demonstrated treatment effects favoring BKP, with variations only in the magnitude of benefit.

The certainty of evidence for reducing disability due to back pain at 3, 6, and 12-month follow-up was moderate. Given the statistical heterogeneity in effect sizes between studies, as evidenced by high I^2 values, and inconsistent findings across studies (with some studies showing benefit while others showed no effect), the evidence was downgraded by one level due to inconsistency. Although the overall risk of bias assessment was high or unclear across one or more domains in the included studies when examining, specifically, disability outcomes (ODI and RMDQ), it was unlikely these measurements were influenced by the identified biases.

The evidence regarding the risk of new vertebral compression fractures after BKP compared to conservative treatment is inconclusive based on the reviewed data. The evidence was downgraded to moderate due to imprecision as the 95 % confidence intervals for the odds ratios include 1.0 and range as high as 3.64 and as low as 0.51 (See Fig. 4 and Table 2).

5. Discussion

This meta-analysis revealed that BKP provides superior pain relief compared to conservative treatment, with benefits sustained throughout the 12-month follow-up period. This finding extends previous evidence that had primarily demonstrated only short-term advantages [12,13]. The magnitude of pain reduction compared to conservative treatment diminished over time, though BKP remained statistically superior at all time points. Similarly, BKP has a maximal effect on disability scores during the first 3 months, which becomes less pronounced during extended follow-up.

The gradual attenuation of treatment effects of BKP in these studies may reflect the prolonged natural healing process of OVCFs, though this relationship is complex. Pain persistence after OVCF can occur despite radiographic healing due to multiple factors, including poor bone mineral density, facet joint changes, and thoracolumbar fascia injury [31]. Additionally, the healing process itself varies with bone quality and can be complicated by continued microfractures or new fractures at the same segment [32]. Conversely, it is possible that the early reported benefit from BKP on pain scores may reflect a satisfactory response of OVCF pain, while later scores are confounded by increased reporting of a patient's coexisting musculoskeletal pain [2].

The present analysis contributes to the established evidence supporting vertebral augmentation procedures. A three-arm Bayesian network meta-analysis by Zhu et al. comparing BKP, vertebroplasty, and non-surgical care demonstrated consistent advantages of these interventional approaches for pain relief, functional improvement, and quality of life [13]. The study showed that BKP had the highest probability (52.67 %) of being the most effective for improving SF-36 PCS scores and demonstrated superior effectiveness (67.92 % probability) in preventing re-fractures at the treated vertebral level. These conclusions were based on limited direct comparison data, with only two studies and a total of 500 patients directly comparing BKP to conservative treatment. Similar meta-analyses have provided comparable results. Halvachizadeh et al.'s systematic review and meta-analysis of RCTs revealed that BKP significantly improved pain versus conservative treatment, with the greatest benefits observed at short-term follow-up (1.31-point improvement on VAS) [12]. For quality-of-life measures, BKP demonstrated higher probability (52.67 %) of improving SF-36 PCS scores compared to conservative treatment. These conclusions, however, stemmed from limited direct BKP versus conservative treatment comparisons, with only one trial (N = 300) specifically examining this comparison.

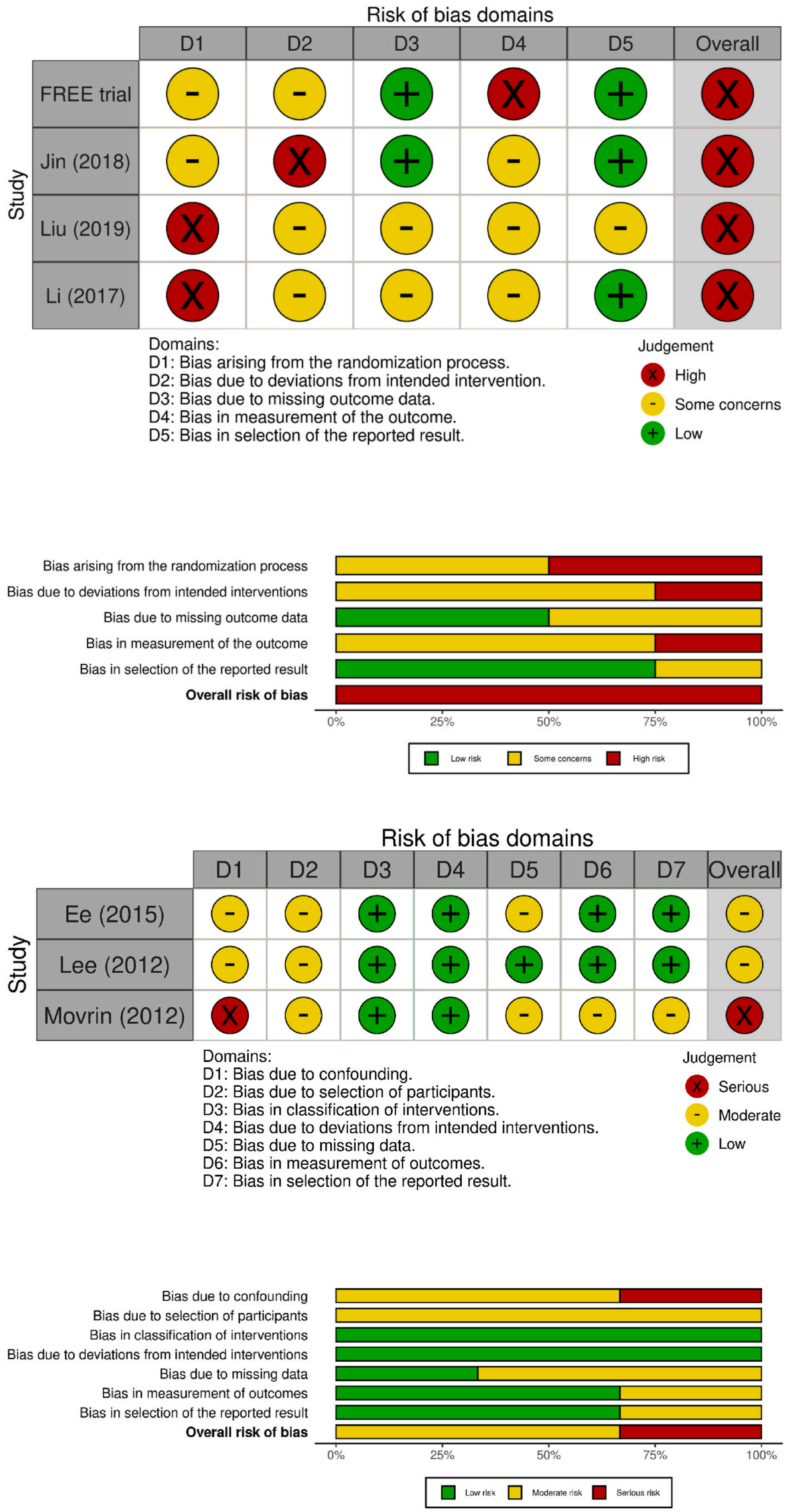

Fig. 5. Risk of bias assessment.

Table 2
GRADE.

Outcomes	Studies (Participants)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Overall certainty of evidence
Pain (VAS)							
Follow-up: 1 month	6 studies (917)	Serious	Not serious	Not serious	Not serious	Not serious	⊕⊕⊕◯ [a]Moderate
Follow-up: 3 months	4 studies (603)	Serious	Not serious	Not serious	Not serious	Not serious	⊕⊕⊕◯ [a]Moderate
Follow-up: 6 months	4 studies (695)	Serious	Not serious	Not serious	Not serious	Not serious	⊕⊕⊕◯ [a]Moderate
Follow-up: 12 months	4 studies (614)	Serious	Not serious	Not serious	Not serious	Not serious	⊕⊕⊕◯ [a]Moderate
Disability (RMDQ, ODI)							
Follow-up: 1 month	3 studies (605)	Not serious	Not serious	Not serious	Not serious	Not serious	⊕⊕⊕⊕ High
Follow-up: 3 months	3 studies (562)	Not serious	Serious	Not serious	Not serious	Not serious	⊕⊕⊕◯ [b]Moderate
Follow-up: 6 months	2 studies (477)	Not serious	Serious	Not serious	Not serious	Not serious	⊕⊕⊕◯ [b]Moderate
Follow-up: 12 months	2 studies (466)	Not serious	Serious	Not serious	Not serious	Not serious	⊕⊕⊕◯ [b]Moderate
Incident new vertebral fractures							
Follow up: latest reported	4 studies (743)	Not serious	Not serious	Not serious	Serious	Not serious	⊕⊕⊕◯ [c]Moderate

[a] Evidence was downgraded by one level due to a high risk of bias.
[b] Evidence was downgraded by one level due to inconsistency.
[c] Evidence was downgraded by one level due to imprecision.

Prior evidence comparing BKP with conservative treatment has been limited by insufficient inclusion of adequately powered trials with extended follow-up periods [8–11]. For example, the systematic review and meta-analysis by Papanastassiou et al. evidenced that BKP provided superior pain relief compared to conservative treatment, showing a 5.07-point greater improvement on the VAS (95 % CI: 4.37–5.77, $P < 0.01$) both short-term (within 8 weeks) and long-term (up to 2 years). Quality of life measures significantly favored BKP over conservative treatment across all follow-up periods (SMD: 0.86; 95 % CI: 0.47–1.25). However, the analysis included only one randomized trial with 300 total patients directly comparing BKP to conservative treatment [8]. Similarly, Sanli et al.'s meta-analysis of 18 prospective controlled trials in patients over 65 years showed BKP provided greater pain relief versus conservative treatment at 6 months (MD: 0.39; 95 % CI: 0.57 to −0.20) with sustained benefits at 12 months; these findings were also limited by including only two direct comparison trials [9]. In contrast, other authors have not identified significant differences between the two treatment options for pain improvement [10] and quality of life [11].

Two studies have assessed the mortality risk associated with vertebral fractures and management with vertebral augmentation. The first, by Ediden et al., reviewed 100 % of the 2005-8 Medicare data set, including 858,978 patients with vertebral compression fractures [33]. In this set, at 4 years, the survival rate of untreated patients was 50 %, compared with 57.3 % for patients treated with vertebroplasty and 62.8 % for patients treated with BKP. The second study, by Ong, reviewed 100 % of the 2005-14 Medicare data set, including 2,077,944 patients with vertebral compression fractures [34]. Similarly, the 10-year mortality risk was 7 % lower for patients treated with vertebroplasty and 19 % lower for patients treated with BKP. Hirsch et al. used data from the Ong study to calculate the number of patients needed to treat (NNT) to save a life [7]. At 1 year, 15 patients treated with BKP will save a life; at 5 years, the NNT is 12. Recent studies have identified contrasting survival patterns. A two-center comparative study ($N = 208$) found no significant mortality benefit for BKP after frailty adjustment ($P = 0.59$) [35]. Gutiérrez-González et al.'s analysis of elderly patients ($n = 492$, age >65 years) similarly showed no survival advantage for vertebral augmentation versus conservative treatment ($P = 0.170$) [36]. This suggests that mortality risk appears more closely linked to demographic and physiologic factors than to the treatment effects of BKP.

Patient-reported outcomes, including pain, function, and quality of life, are all important for considering the long-term benefit of procedures such as BKP. Patients who underwent BKP showed significant improvement in functional outcomes compared to those receiving conservative treatment. This improvement was sustained for 6 months in one study [23] and 12 months in another [28]. However, more research will be necessary to estimate combined effects. Only the FREE trial evaluated quality of life, demonstrating statistically significant improvements sustained by BKP and maintained at long-term follow-ups (24 months) [22–24].

This review found no differences in the risk of new vertebral fractures between BKP and conservative treatment. This finding is consistent with previous meta-analyses that demonstrated nonsignificant differences in fracture risk between BKP and conservative treatment [29,37].

6. Limitations

The search was limited to literature in English, which may bias results by limiting the search scope and excluding some potentially high-quality relevant research articles. Strict inclusion criteria were implemented to consolidate the best evidence available, considering only studies with large sample sizes. However, by doing so, some studies that may have provided additional information were excluded. Comparative studies with fewer than 100 participants were excluded, and their data were not extracted for sensitivity analyses. Although we intentionally decided to include only larger prospective comparative studies, results from smaller studies may be relevant to broader conversations about the effectiveness of BKP compared to conservative treatment.

7. Conclusion

According to GRADE, moderate certainty evidence suggests that BKP is superior to conservative treatment for the treatment of painful OCVFs in terms of pain reduction, with the largest benefit observed at 1 month and continued, albeit smaller, benefit sustained up to 12 months. For disability improvement, BKP demonstrates high and moderate-certainty evidence of superiority over conservative treatment, with significant benefits up to 3 months. Evidence regarding the risk of adjacent compression fractures remains inconclusive based on the reviewed data, and further research is needed to better assess this outcome.

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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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