A Randomized Controlled Trial: Short-Segment Posterior Fixation and Transpedicular Bone Grafting combined with rhBMP-2 for the Treatment of Thoracolumbar Burst Fracture

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Abstract

Purpose

The current study presents a novel treatment strategy involving short-segment posterior fixation and transpedicular bone grafting combined with recombinant human bone morphogenetic protein-2 (rhBMP-2). The aimed is to investigate the clinical efficacy in treating thoracolumbar burst fracture (TLBF).

Methods

Patients with acute TLBF requiring surgical treatment were conducted. Enrolled patients were randomly assigned to either the intervention or control groups. All patients underwent short-segment posterior fixation treatment, with the intervention group receiving additional transpedicular bone grafting and rhBMP-2 into the fractured vertebral body using vertebroplasty instrumentation. In contrast, the control group did not undergo any bone implantation procedures. Preoperative and postoperative imaging indices, including Sagittal Cobb Angle (SCA) and Anterior Vertebral Height Ratio (A VHR), as well as fracture healing rate, were assessed. Treatment indices, such as the visual analog scale (VAS), were also measured. Furthermore, general information was compared between the two groups.

Results

There were 24 patients enrolled in the intervention group, and 36 patients in the control group. Demographic data showed no significant differences between groups ($P > 0.05$). One year after the operation, the SCA was significantly lower in both groups compared to the preoperative period. However, the intervention group exhibited less loss in SCA compared to the control group at the 1-year follow-up ($P < 0.05$). There was no significant difference in the anterior A VHR between the two groups at 7 days, 3 months, and 1 year after operation ($P > 0.05$). Regarding the fracture healing rate, the postoperative Lane-Sandhu scores of both groups increased significantly. At 3 months after surgery, the observation group showed a significantly higher score than the control group ($P < 0.05$).

Conclusion

This RCT demonstrated that the short-segment posterior fixation and transpedicular vertebral bone graft combined with rhBMP-2 can effectively reduce the SCA and accelerate fracture healing.

1. Introduction

Thoracolumbar burst fracture (TLBF), primarily caused by traffic accidents and falls from height, is a severe spinal injury, with approximately 50% of TLBFs occurring at the thoracolumbar junction[1]. The treatment of TLBF remains a crucial and controversial issue due to the severe clinical outcomes associated with it, such as spinal instability [2]. There remains controversy regarding the optimal treatment strategy for TLBF[3]. Overall, patients with a Thoracolumbar Injury Classification System (TLICS) score of more than four or an AO spine score of more than five are recommended to undergo surgery[4][5]. Among them, posterior surgery, represented by pedicle screw internal fixation, is widely utilized as a classical procedure[6].

However, despite the effectiveness of simple short-segment internal fixation in resetting collapsed vertebrae and restoring the height of the injured vertebrae by relaxing the posterior ligamentous complex and muscles with the assistance of muscle relaxants, and by using "nail rods" to open the vertebrae, the cancellous bone in the injured vertebrae, squeezed by external forces, tends to form cavities, resulting in the so-called "eggshell effect"[7]. These effects leads to the loss of vertebral body height and posterior convexity of Cobb's angle, causing lower back, loss of vertebral height, and other symptoms. Scholars believe that bone grafting in the vertebral body of injured vertebrae can enhance the internal mechanical strength, promote the healing of cancellous bone, and reduce the loss of correction.

According to Dennis's three-column theory, this stability of the spine mainly relies on the anterior and middle columns, with the posterior column contributing only about 20%. Over a decade ago, there was growing interest among orthopedic surgeons in a surgical approach aimed at strengthening the stability of the anterior and middle columns of the spine through posterior short-segment internal fixation combined with intravertebral bone grafting [8][9]. Recent studies have suggested that bone grafting within the vertebral body of an injured vertebra enhances internal mechanical strength, promotes cancellous bone healing, and reduces correction loss[10].

Recently, biomaterials have garnered scholarly attention, and one noteworthy biological reagents is recombinant human bone morphogenetic protein-2 (rhBMP-2)[11]. It has been shown that rhBMP-2 can promote bone healing, increase the rate of spinal fusion, facilitate postoperative recovery for patients, and improve their overall quality of life. While rhBMP-2 is extensively utilized in trauma surgery, there has been comparatively less research conducted on its application in spinal fractures.

Based on the abovementioned background, this study introduced a novel treatment strategy involving short-segment posterior fixation and transpedicular bone grafting combined with rhBMP-2. The objective was to investigate the clinical efficacy of this approach for TLBF.

2. Methods

2.1 Study population

This study prospectively enrolled consecutive patients with TLBF admitted to the First Affiliated Hospital of Chongqing Medical University from December 2020 to May 2023. The diagnosis of TLBF was established through clinical symptoms, physical examination, and imaging studies. The inclusion and exclusion criteria for patient selection are listed in Table 1. In addition, all patients received and signed the informed consent before participating in this study.

Table 1
Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Fresh single-segment thoracolumbar burst fracture	1. Old fractures
2. TLICS score[12] Greater than 4 points	2. Multiple vertebral fractures
3. Regular follow-up	3. Non-T10-L3 segmental fractures
4.Preoperative examination to exclude contraindications to surgery	4. Osteoporotic fracture (DXA T-score ≤-2.5SD)[13]
5. At least one side of the pedicle is intact	5. Patients with pathological fractures
6. Absence of spinal neurological symptoms or incomplete symptoms (Frankel score grade C, D, E)[14]	6. Paraplegics

TLICS score, thoracolumbar injury classification and severity score: spinal fracture pattern (1 point for compression, + 1 point for burst, 3 points for displacement or rotation, and 4 points for subluxation), neurologic status (0 points for intact, 2 points for nerve root injury, 2 points for complete spinal cord injury, and 3 points for incomplete spinal cord injury or cauda equina syndrome), and posterior ligamentous complex integrity (0 points for intact, 2 points for suspected injury, and 3 points for injury);T10, the tenth thoracic vertebra; L3, the third lumbar vertebra; DXA, Dual-emission X-ray Absorptiometry, T-score ≤-2.5SD means Osteoporotic; SD, standard determination; Frankel score: Grade A, complete loss of sensory and motor function below the plane of injury; Grade B, no motor function below the plane of injury, with only some sensory function; Grade C, only some useless motor function below the plane of injury; Grade D, useful motor function below the plane of injury, but incomplete; Grade E, normal sensory, motor, and sphincter function.

2.2 Trial design

This study is a prospective, randomized clinical trial performed in one hospital. The protocol for this study was approved by the Ethical Review Committee of the First Affiliated Hospital of Chongqing Medical University (No. ChiCTR2200061173). Randomization in this study was performed using a simple, equal probability randomization scheme. Patients were assigned to either the intervention group (short-segment posterior fixation and transpedicular bone grafting combined with rhBMP-2) or the control group (short-segment posterior fixation) by a simple, equal probability randomization scheme.

2.3 Surgical procedure

All enrolled patients underwent open decompression and short-segment internal fixation through a standard posterior midline approach. These procedures were performed by a single surgeon within 7 days of the initial trauma. Anesthesia was administered using tracheal intubation with sedation-aspiration complex anesthesia. After successful anesthesia, the patients were positioned prone with padding and abdominal suspension. Following routine disinfection and toweling, a posterior median incision was made, centered on the injured vertebrae and the two segments above and below. Sequentially, the skin and subcutaneous tissue were incised, exposing the injured vertebrae and the upper and lower two segments of the articular synovial joints bilaterally through the multifidus and longest muscle interspaces. Screws were then inserted into the two segments above and below injured vertebrae. Vertebroplasty cannulas (Shandong Guanlong) were inserted into the roots of the injured vertebrae's arches. Autogenous crushed bone particles, allogeneic bone (Hangzhou Hongli, one box) and recombinant BMP (Hangzhou Jiuyuan, 0.5 g) were implanted into the injured vertebrae under the C-arm fluoroscopy guidance. A mixture of autogenous bone particles, allograft bone (Hangzhou Hongli, 1 box), and recombinant BMP (Hangzhou Jiuyuan, 0.5 g) was further implanted into the injured vertebral body along bilateral working cannulae under C-arm fluoroscopy. Once the bone grafting situation was satisfactory, the working cannulae were removed, screws were placed in both vertebral pedicles, and titanium alloy rods of the appropriate length were installed and fixed to achieve vertebral body support and realignment. Finally, ordinary pressure drainage tubes were placed on both sides of the wound, and the wound was closed layer by layer with sutures.

2.4 Postoperative rehabilitation

Postoperatively, patients received antibiotics for 24 hours to prevent infection. Pneumatic pumps were applied to the lower limbs to prevent thrombosis. Analgesia and other symptomatic treatments were administered as needed. The postoperative drainage volume of less than 50 mL in 24 hours was considered as the standard for the removal of the drainage tube. Dressings were changed every 2–3 days, and it was recommended to either keep absorbable sutures in place post-surgery or remove them after 14 days. Upon discharge from the hospital, patients were advised to rest for three months, with the first month spent primarily in bed rest. Subsequently, they were instructed to gradually resume activity while wearing a lumbar brace for support, which was recommended for use over the following two month. We encouraged the patients to initiate ankle flexion and extension exercises and lower limb activities starting on the first postoperative day. Non-weight-bearing training of the lower back muscles was initiated in bed under the supervision of a healthcare provider after drainage tube removal. X-ray, CT scans, and clinical evaluation were performed at one week, three months, 12 months post-surgery, as well as before and after removal of the internal fixation.

2.5 Outcome measures

All patients underwent follow-up assessments lasting 12–18 months, with one month after the removal of internal fixation serving as the endpoint. Regular thoracolumbar spine X-rays and 3D-CT examinations were conducted during these follow-up sessions. The general data, clinical data, and imaging indexes of the two groups were compared and analyzed. The general data included gender, age, and body mass index. Clinical data primarily focused on the duration of the main operation, intraoperative blood loss, length of hospital stay, fracture healing rate (assessed using Lane-Sandhu X-ray score[15]), and neurological complications (evaluated using Frankel's neurological function[14]). Imaging indexes included the Anterior Vertebral Height Ratio (%) (A VHR, which represents the ratio of the anterior height of the fractured vertebra to the mean anterior height of the adjacent upper and lower vertebrae (%)), and the Sagittal Cobb Angle (SCA).

2.6 Statistical analyses

Statistical analysis was performed using SPSS software (version 20.0). Quantitative data are presented as median ± standard deviation, while frequencies and percentages were calculated for qualitative data. Student’s t-test was employed for continuous data, and the $\chi 2$ test was utilized for categorical data to compare variables between the two groups. The significance level was set at $P < 0.05$.

3. Results

3.1 Baseline characteristics

Of 75 consecutive patients with TLBF, 65 patients were initially included in this study. Subsequently, 5 patients were excluded, resulting in 60 patients available for analysis (The detail of the CONSORT diagram for this study is found in Fig. 1). Ultimately, the final analysis comprised 24 patients in the intervention group and 36 patients in the control group. The interval time from injury to surgery showed no significant difference between the groups, as well as other demographic data (gender, age, BMI, $P > 0.05$). Regarding the cause of injury and the injured segment, patients in the intervention group were similar to those in the control group ($P > 0.05$) (Table 2).

Table 2
Comparison of baseline characteristics

		Intervention group (N = 24)	**Control group (N = 36)**	**P-value**
Age	(year)	53.41 ± 2.43	51.30 ± 1.83	0.483
Gender	(M/F)	16/8	22/14	0.662
BMI	(kg/m^2)	22.73 ± 0.59	24.14 ± 0.92	0.254
Injury to surgery time	(day)	7.04 ± 1.18	5.33 ± 0.40	0.118
Cause of injury	Falling	21	31	0.242
	Traffic accident	3	3	
	Bruise	0		
Injured segment	T12	3	4	0.920
	L1	11	16	
	L2	8	10	
	L3	1	3	
	L4	1	3	

M male; F female; T thoracic vertebra; L lumbar vertebrae

3.2 Perioperative parameters

There were no statistically significant differences between the two groups in terms of operation time, intraoperative bleeding, drainage on the first postoperative day, and length of hospital stay ($p > 0.05$). As for the VAS, there are also there was no statistically significant difference. However, the operation time in the control group was significantly shorter than that in the intervention group ($P < 0.05$).(Table 3).

Table 3
Comparison of perioperative parameters between the two groups (± s)

		Intervention group (N = 24)	**Control group (N = 36)**	**P-value**
Surgical time	(min)	157.04 ± 13.30	122.42 ± 8.96	0.029
Intraoperative hemorrhage	(ml)	137.92 ± 26.78	95.00 ± 14.57	0.133
Postoperative drainage on day 1	(ml)	84.58 ± 11.48	106.38 ± 17.60	0.282
Length of hospital stay	(day)	13.75 ± 1.93	12.17 ± 1.13	0.453
VAS		2.5 ± 0.12	2.39 ± 0.12	0.536
Preoperative		1.96 ± 0.15	1.94 ± 0.07	0.935
7 days postoperative		1.58 ± 0.10	1.64 ± 0.13	0.742
3 months postoperative		0.58 ± 0.12	0.75 ± 0.08	0.242
1 year postoperative				

3.3 Comparison of impact indicators

During the follow-up period, postoperative A VHR **(%)** was higher than preoperative values in both groups. However, there was no statistically significant difference between the two groups for preoperative A VHR (%), as well as 7 days, 3 months or one year after surgery. Regarding the SCA, it was lower than the preoperative value in both groups during the follow-up, with a statistically significant difference ($P > 0.05$). The difference in SCA between the two groups one year after surgery was statistically significant ($P < 0.05$). The fracture healing rate was not significantly different between the two groups at 7 days after surgery ($P < 0.05$). However, three months after surgery, the fracture healing was faster in the observation group, with the difference being statistically significant ($P < 0.05$). (Table 4.)

Table 4
Comparison of impact indicators between the two groups (± s)

	Intervention group (N = 24)	**Control group (N = 36)**	**P-value**
AVHR (%)	16.00 ± 1.34	18.08 ± 0.56	0.119
Preoperative	21.70 ± 0.62	22.15 ± 0.33	0.479
7 days postoperative	20.39 ± 0.72	20.50 ± 0.49	0.912
3 months postoperative	20.05 ± 1.23	20.79 ± 0.70	0.591
1 year postoperative			
SCA			
Preoperative	7.62 ± 1.69	9.65 ± 1.63	0.403
7 days later	4.28 ± 0.89	4.35 ± 0.65	0.951
3 months later	8.32 ± 1.66	6.99 ± 0.9	0.462
1 year later	5.37 ± 1.45	9.79 ± 1.10	0.041
Lane Sandhu X-ray scores	2.21 ± 0.17	2.31 ± 0.12	0.639
7 days postoperative	6.54 ± 0.19	4.83 ± 0.13	0.001
3 months postoperative			

3.4 Complications and implant fusion

There were no major complications observed in either groups, including wound infection, nerve injury, or failure of internal fixation.

4. Discussion

To our knowledge, this study was the first randomized RCT evaluating the efficacy of short-segment posterior fixation and trans-articular bone grafting combined with rhBMP-2 for TLBF surgery. The main findings of this study revealed that this surgical approach effectively reduces the SCA and accelerates fracture healing.

An ideal bone graft material should fulfill several functions, including promoting bone formation, inducing bone growth, and facilitating bone reconstruction[16]. While autogenous bone is considered an ideal graft material, only relying on intraoperative harvest from the vertebral body and iliac crest may often be insufficient to meet the demand for bone grafting during surgery. This method of taking the iliac bone not only prolongs the operation time but also subjects the patients to secondary injury, increasing pain to the patient. In severe cases, it can also lead to iliac neurovascular injury [17]. It has been pointed out that the fusion rate of autologous bone grafts also varies greatly. With the development of biomaterials, allograft bone has been widely used[18]. However, concerns have been raised regarding the risk of immune rejection associated with allogeneic bone grafts [19]. However, similar complications were not observed in the intervention group during our follow-up.

Significant osteogenic effects can promote bone healing, increase the rate of spinal fusion, facilitate patients' postoperative recovery, and improve the quality of life[20]. However, current studies have not identified the optimal ratio of platelets to other bone marrow cells in PRP. It has been suggested that a platelet dose greater than 1.3×106 cells/μL is more favorable for bone fusion[21]. Besides, in clinical practice, the extraction of sufficient numbers of bone marrow platelets requires advanced equipment and technology, posing limitations on its application and promotion[22].

The safety of using rhBMP-2 has become an increasing concern due to numerous reports in the literature that the use of rhBMP-2 can lead to adverse effects such as delayed wound healing, infection, hematoa, radiculitis, and dysphagia[23]. Furthermore, a large retrospective study in 2013 demonstrated an association between the use of rhBMP-2 in lumbar fusion and an increased incidence of benign tumors [24]. In our study, a low dose of rhBMP-2 (0.5 mg) was used, and screws were implanted immediately after the completion of bone grafting, confining the rhBMP2 to the injured vertebral body. This approach effectively minimized the biological effects of rhBMP-2 on the surrounding and mitigated the risk of adverse events. No such adverse events were observed during our follow-up period. In our study, the Lane-Sandhu ray scores of the observation group were significantly higher than those of the control group at 3 months postoperatively ($P < 0.05$). This finding confirms that rhBMP-2 enhances the osteogenic capacity of bone and promotes fracture healing.

Compared to traditional posterior short segmental nail and rod fixation combined with nail rod spreading, the implantation of autogenous fragmented bone particles and allograft bone with rhBMP-2 via the pedicle offers several advantages. This approach better fills the height of the vertebral body and addresses the cavity caused by bone loss in the vertebral body after the fracture. It enhances the stability of the anterior and middle columns of the injured vertebrae, restores vertebral body height, enhances the compression resistance of the injured vertebrae, promotes the healing of the fracture, and reduces the risk of loss of height caused by the internal fixation. Furthermore, this technique reduces the incidence of broken nails and rods due to excessive stress in internal fixation, as well as the incidence of postoperative vertebral collapse. Consequently, it significantly decreases the risk of height loss in reduction fractures resulting from early postoperative movement. During follow-up, while the difference in AVHR (%) between the two groups was not statistically significant, a significant difference in SCA between the two groups was observed at one year. Specifically, the intervention group demonstrated significantly better outcomes compared to the control group.

The mechanism by which allogeneic bone mixed with rhBMP-2 promotes fracture healing may be that allogeneic bone provides a scaffolding structure in the injured vertebrae, which promotes migration and proliferation of osteoblasts in addition to helping to maintain the stability of the fracture site [25]. In contrast, rhBMP-2 mainly promotes the differentiation of stem cells, stimulates the proliferation of cartilage and osteoblasts, accelerates the rate of new bone tissue generation, improves bone matrix protein synthesis, promotes angiogenesis, and provides the nutrients and oxygen needed in the fracture healing process, thus facilitating the process of fracture healing (Fig. 2) [26–29].

In previous studies, researchers have explored different methods of bone grafting in injured vertebrae. One such method is the "transpedicular bone grafting", where short-segment pedicle screws are used to fix the injured vertebra along with the upper and lower vertebrae. Subsequently, a pedicle screw on one side of the injured vertebra is removed to create a channel for bone graft implantation using either autogenous or allogenic bone. Finally, the removed screw is re-implanted into the injured vertebra. This technique does not require additional surgical instruments; however, the angle of the pedicle root is already determined during screw implantation, making it challenging to transplant bone into the middle third of the vertebral body. This limitation often results in insufficient bone implantation, leading to reduced healing rates of the injured vertebrae and potentially affecting clinical outcomes. Moreover, transpedicular bone grafting requires the secondary placement of pedicle screws, which not only prolongs surgical time but also increases the risk of internal fixation instability. This instability may ultimately lead to the loss of height of the injured vertebra.

Some scholars have also proposed the Kambin's triangle bone grafting method, which utilizes a specific "bone grafting funnel" to create a channel for bone grafting through the lower edge of Kambin's triangle and the upper edge of the pedicle after internal fixation. This technique allows the bone graft to reach the anterior 1/3 of the opposite side of the injured vertebra by puncturing from the side of the injured vertebra. This implantation method not only enlarges the scope of implantation but also enables adjustment of the implantation angle in multiple directions, to better rebuild the stability of the anterior and middle column of the fractured vertebral body. Additionally, the mechanical prying action of the "implantation hopper" can help reset the collapsed vertebral body, restore the height of the injured vertebrae, and achieve satisfactory correction of kyphosis, promoting bone healing. This can effectively reduce the neurological complications caused by bone defects and bone nonunion after surgery[30]. However, Kambin bone grafting has limitations such as puncturing into the injured vertebrae, re-destruction of the vertebral bone cortex, cumbersome surgical steps, difficulty in obtaining "bone grafting funnel" instruments, and prolonged surgical time. In responses to these challenges, some scholars have pointed out the use of a new type of transforaminal pedicle decompressor for transforaminal bone grafting. This device restores the height of the injured vertebrae through expansion upon entering the injured vertebrae and then implants the bone. This device is similar to the balloon used in vertebral kyphoplasty, but further clinical efficacy needs to be further verified. Hence, our study utilized a new bone grafting method [18][31].

During surgery, before implanting screws into the injured vertebrae, we utilize the working canal of vertebroplasty instrumentation to perform bone grafting via the pedicle[32]. This approach minimizes damage to the vertebral body, as the working tube of the vertebroplasty instrumentation causes little harm. After implantation, the screws are implanted through the original channel, enlarging the nail channel without affecting the holding power of the screws. Moreover, the implant material is inserted into the vertebral body through the working channel, allowing for pressurization to compact the implant material more compact and distribute it evenly. The vertebroplasty instruments used in our study are commonly used in percutaneous perforated vertebroplasty in spine surgery and are easily accessible. In our study, the longer operating time in the observation group was longer than that of the control group. The reason for this may be attributed to the additional surgical step of bone grafting, which increased the intraoperative waiting time for C-arm fluoroscopy.

There are several limitations to our study approach. Firstly, this was a single-center study with a relatively small number of included cases. Second, our study did not provide long-term follow-up or interventions for the included study subjects after surgery, and information was only collected at a particular follow-up time point. Thirdly, there are no specific criteria for evaluating fracture healing rates, and our study utilized the Lane-Sandhu ray scores for scoring, which, although evaluated by two physicians, may introduce subjectively into the assessment. Therefore, prospective studies with larger sample sizes are needed to further validate its clinical efficacy.

5. Conclusion

The strength of our study lies in the homogeneity of the enrolled patients, who underwent the same surgery performed by the same surgeon in the same hospital. The results of this study provide evidence for a safe and effective treatment strategy for the surgical management of TLBF. This strategy effectively reduces SCA and accelerates fracture healing without increasing the risk of complications. These findings are beneficial for enhancing postoperative recovery and improving patient outcomes

Declarations

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Author Contribution

No conflict of interest exits in the submission of this manuscript, and manuscript is approved by all authors for publication. I would like to declare on behalf of my co-authors that the work was a propensity score matching analysis that had not been published previously, and not under consideration for publication elsewhere, in whole or in part. Zhen-ming Hu has conceived the study, and Ming-huang Cheng has written the first draft.

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Figures

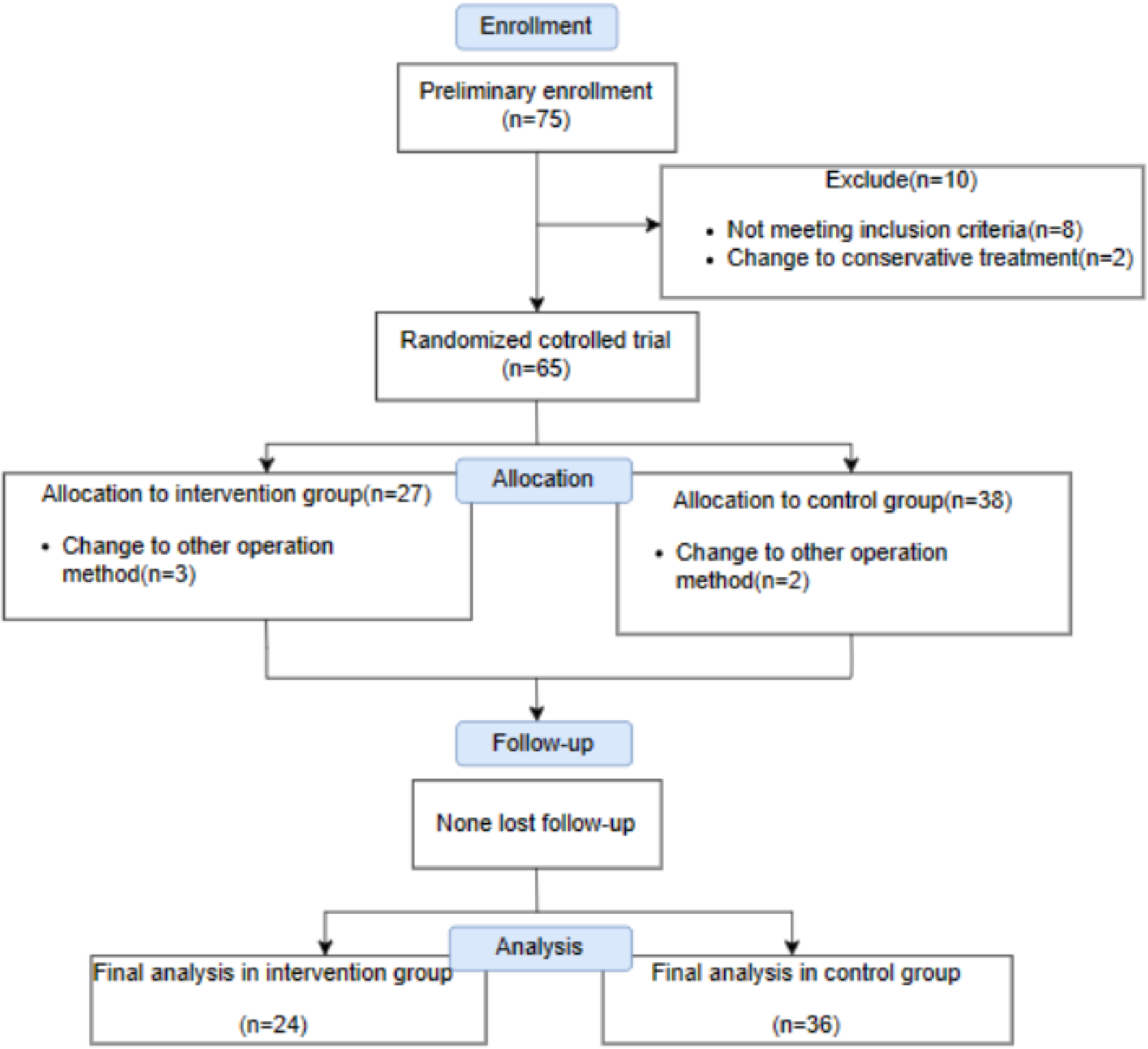

Figure 1

Flowchart of the selection process of patients

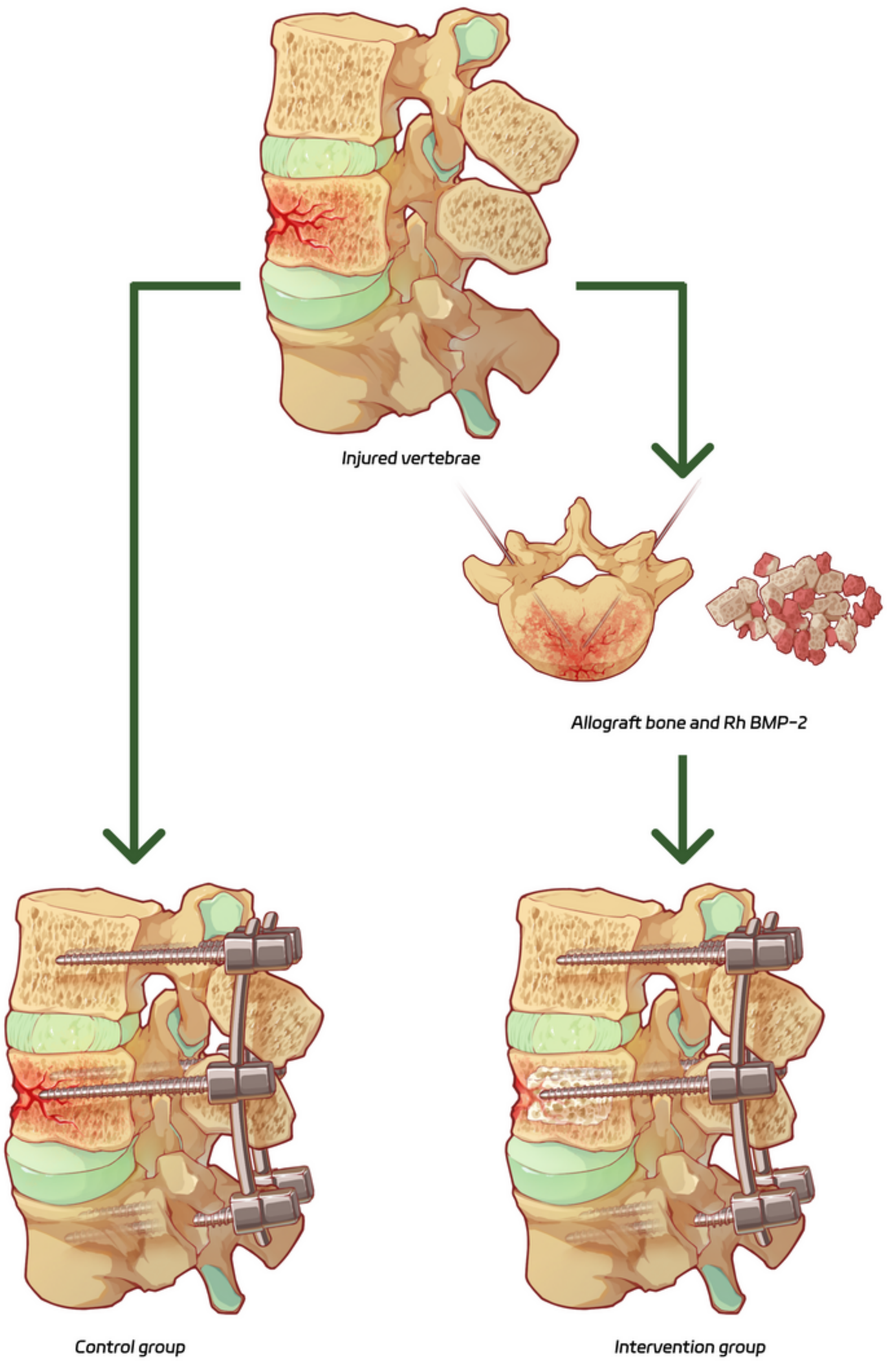

Figure 2

Mechanisms of Allograft Bone and rhBMP-2 for Vertebral Fracture Healing