Standardized Study Protocol of Percutaneous Vertebroplasty Based on Pedicle Nine-Grid Zoning Method

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1. Study Background

Transpedicular percutaneous vertebroplasty (PVP) is the preferred surgical procedure for the treatment of osteoporotic vertebral compression fractures. The traditional ideal bony puncture point for lumbar puncture is located at the "10 o’clock (left) and 2 o’clock (right)" position of the pedicle projection. Conventional intraoperative puncture relies heavily on individual surgeon experience and repeated C-arm fluoroscopy, resulting in a long learning curve for novice surgeons. Based on extensive preliminary clinical and imaging research, our team found that the traditional single ideal bony puncture point for lumbar transpedicular PVP can be expanded to multiple ideal bony puncture surfaces. Accordingly, we proposed the innovative concept of the pedicle nine-grid zoning method for identifying the optimal bony puncture surface of lumbar pedicles.

This study consists of three parts: retrospective imaging analysis, model verification using the PHACON surgical navigation training system (Germany), and a prospective clinical randomized controlled trial. It aims to systematically evaluate the safety and efficacy of the nine-grid zoning method in lumbar transpedicular PVP. The study is expected to establish a novel, safe, and effective standardized transpedicular puncture approach for PVP, reduce intraoperative fluoroscopy frequency and operative time caused by repeated puncture adjustment in traditional PVP, and ultimately improve overall surgical efficiency and clinical outcomes.

2. Study Objectives

1. To further verify the safety and efficacy of unilateral transpedicular PVP assisted by the pedicle nine-grid zoning method through a prospective randomized controlled clinical trial.

2. To clarify the surgical indications, standardized operational procedures, and standardized perioperative management protocols for this novel puncture technique.

3. Study Content

3.1 Study Hypothesis

The novel standardized PVP surgical approach based on the lumbar pedicle ideal bony puncture surface defined by the nine-grid zoning method is safe and effective. This technique can significantly reduce intraoperative fluoroscopy times and operative time required for puncture position adjustment in conventional PVP, thereby improving surgical efficiency and clinical efficacy.

3.2 Research Foundation

The Department of Orthopedics, Beijing Friendship Hospital, Capital Medical University, is one of the earliest domestic institutions engaged in in-depth research on the diagnosis and treatment of osteoporosis. It is also a pioneer in carrying out vertebroplasty and kyphoplasty for osteoporotic vertebral compression fractures in China, with more than 5,000 relevant surgeries completed since 2003.

The department has undertaken more than 10 national and provincial research projects related to osteoporosis, obtained 1 national scientific and technological achievement award and 2 Beijing municipal scientific and technological achievement awards, and undertaken 3 national continuing education programs. Multiple national continuing education training courses on surgical treatment of osteoporotic fractures have been successfully held. In 2009, the department was designated as a national diagnosis and treatment base for osteoporosis by the National Health Commission and Chinese Medical Doctor Association, and was upgraded to the National Diagnosis and Quality Control Standard Test Base for Osteoporosis in September 2012.

The department has been equipped with dual-energy X-ray absorptiometry (DXA) since 1998, ranking among the earliest hospitals in China with this equipment. A specialized osteoporosis clinic has been available since 2008. The annual outpatient volume of the orthopedics department reaches 150,000 to 200,000 visits, with tens of thousands of high-risk osteoporosis cases annually. The department performs 600 to 800 vertebroplasty procedures per year.

All core research members have long-term experience in clinical and basic research on osteoporosis, with no major surgical errors or medical disputes in recent years. All team members have experience in presiding over or participating in provincial and national scientific research projects, with strong scientific research capabilities and coordination skills. Most researchers hold master’s degrees or above, with excellent teamwork awareness, fully meeting the talent and hardware requirements for project implementation.

4. Study Protocol

4.1 Study Design

Prospective randomized controlled clinical trial

4.2 Study Population

Study Subjects: Inpatients diagnosed with lumbar osteoporotic vertebral compression fractures who underwent surgical treatment in the Department of Orthopedics, Beijing Friendship Hospital, Capital Medical University, from May 2024 to May 2026.

Study Center: Beijing Friendship Hospital, Capital Medical University

4.3 Sample Size Calculation

It is hypothesized that the rate of achieving ideal intraoperative surgical endpoints is 90% in the modified nine-grid PVP group and 50% in the traditional PVP group. A difference of ≥10% in the ideal endpoint achievement rate between the two groups is defined as clinically significant. With a one-sided significance level of 0.025 and a statistical power of 80%, the calculated sample size is 60 cases (30 cases in each group). Considering an approximately 10% loss to follow-up rate, a total of 68 patients (34 cases in each group) will be enrolled to ensure statistical validity.

Reference: Chow, S.C., Shao, J., and Wang, H. 2008. Sample Size Calculations in Clinical Research, Second Edition. Chapman & Hall/CRC. Boca Raton, Florida.

4.4 Inclusion and Exclusion Criteria

Inclusion Criteria

1. Patients diagnosed with single-segment acute osteoporotic lumbar vertebral compression fracture (L1-L5), with typical MRI manifestations: low signal on T1-weighted imaging and high signal on T2-weighted and STIR sequences;

2. Patients receiving PVP surgery for the first time;

3. Patients with complete preoperative imaging data including X-ray, CT, and MRI/bone scan.

Exclusion Criteria

1. Patients with old osteoporotic vertebral compression fractures or congenital pedicle malformation and lesions;

2. Patients with bone tumors or other systemic bone metabolic diseases;

3. Patients with incomplete or ruptured posterior wall of fractured vertebral body confirmed by CT;

4. Patients who fail to sign informed consent.

4.5 Study Procedures

Eligible inpatients diagnosed with single-segment acute lumbar osteoporotic vertebral compression fractures requiring PVP surgery are randomly divided into the experimental group (nine-grid zoning method assisted PVP) and the control group (traditional puncture PVP). Preoperative, intraoperative and postoperative imaging and clinical data are collected and analyzed uniformly.

Traditional PVP Group Surgical Procedures

1. Routine surgical disinfection, draping and local anesthesia;

2. Determine the puncture site according to the traditional pedicle projection positioning standard (10 o'clock for the left pedicle, 2 o'clock for the right pedicle) under C-arm fluoroscopy;

3. Perform longitudinal skin incision and initial puncture, and adjust the needle position under anteroposterior C-arm fluoroscopy;

4. Fix the puncture needle on the articular process cortical bone, confirm the needle position and depth under lateral fluoroscopy, and advance the needle until breaking through the posterior vertebral edge under fluoroscopic guidance;

5. Reconfirm that the puncture needle is within the medial margin of the pedicle projection under anteroposterior fluoroscopy;

6. Further advance the needle to the anterior 1/3 of the vertebral body (lateral view) and the midline of the vertebral body (anteroposterior view);

7. Complete bone cement mixing, injection and incision suture to finish the operation.

Nine-Grid Zoning Method Assisted PVP Group Surgical Procedures

1. Routine surgical disinfection, draping and local anesthesia;

2. Locate the optimal puncture site and puncture surface based on the pedicle nine-grid zoning method under C-arm fluoroscopy;

3. All subsequent surgical operations are consistent with the traditional PVP group.

All surgeries are performed by the same team of experienced senior spine surgeons. The ideal endpoint achievement rate and operative time are taken as the primary evaluation indicators to verify the safety and efficacy of the nine-grid zoning method, so as to reduce intraoperative fluoroscopy times and operative time caused by repeated puncture adjustment and improve surgical efficiency and prognosis.

4.6 Observation Indicators and Follow-Up Plan

Primary Outcome Measures: Rate of achieving ideal intraoperative puncture endpoints, operative time.

Secondary Outcome Measures: Incidence of postoperative bone cement leakage.

Follow-Up Protocol: All enrolled patients receive standardized postoperative follow-up for 1 year. Free X-ray and CT re-examinations are provided during follow-up,

together with regular health education and clinical guidance.

Preoperative Data Collection: Demographic information (gender, age, height, weight), bone mineral density, disease course, VAS pain score, Oswestry Disability Index (ODI), and SF-36 quality of life score.

Intraoperative Data Collection: Ideal puncture endpoint achievement rate, total operative time, intraoperative fluoroscopy times and radiation dose (mSv), intraoperative bone cement filling status, bone cement leakage condition and classification, and intraoperative complications (spinal nerve root injury, secondary fracture, etc.).

Postoperative Data Collection: VAS scores (postoperative day 1, before discharge, 3 months, 6 months and 1 year after surgery), ODI scores (before discharge, 1 year after surgery), SF-36 scores (before discharge, 1 year after surgery), and incidence of postoperative vertebral re-fracture.

4.7 Informed Consent

All enrolled patients or their legal guardians sign written informed consent before participation.

4.8 Risk Control and Management

The only difference between the experimental group and the control group is the puncture site selection method. The surgical anatomical structures and overall operative risks are consistent with traditional PVP. All surgeries are performed by experienced spine surgeons, and intraoperative puncture feel combined with real-time C-arm fluoroscopy is adopted to reduce surgical risks. In case of difficult puncture or puncture failure, the traditional puncture method will be converted immediately, and all adverse conditions will be truthfully recorded. All technical operations comply with national and local medical regulations with no additional safety risks.

4.9 Data Confidentiality

All subjects' personal information is anonymized for data storage and analysis. All clinical data are kept in strict confidentiality. No individual private information will be disclosed in any published study results.

5. Statistical Methods

All statistical analyses are performed using SPSS 19.0 software. Descriptive statistics are applied to analyze data distribution, outliers, and basic characteristics, including mean value, standard deviation, median, maximum value, minimum value, quartile and constituent ratio.

For statistical inference: Chi-square test is used for rate comparison; independent sample t-test is used for comparison of mean values between two groups; repeated-

measures ANOVA is used for multi-time point data comparison; non-parametric tests are adopted for non-normally distributed data. Pearson or Spearman correlation analysis is used for correlation evaluation. A two-tailed P value < 0.05 is considered statistically significant. All data are imported into a dedicated database and cleaned strictly before final analysis.

6. Quality Control

This study adopts the principal investigator responsibility system and standardized project management. Special clinical monitors conduct regular on-site inspections to ensure strict implementation of the study protocol and accurate data recording.

All clinical trial form (CRF) data are filled in truthfully, completely and standardizedly by researchers. Any modification of original medical records must be attached with detailed explanations, signed and dated by the researcher in charge.

Multiple follow-up reminder measures are adopted to ensure patient compliance and control the case dropout rate within 10%. All laboratory test results are recorded completely, and abnormal data are verified and explained professionally.

The project implements phased rolling management, with regular quarterly assessment. Project funds are allocated by stages according to assessment results to ensure standardized and orderly project progress.

7. Research Team Qualification and Division of Labor

Fei Qi: Chief Physician, overall project responsibility and study protocol design, working time: 12 months.

Lin Jisheng: Attending Physician, retrospective imaging research implementation, working time: 18 months.

Yang Yong: Chief Physician, clinical case collection, working time: 12 months.

Meng Hai: Associate Chief Physician, surgical navigation system model verification, working time: 12 months.

Fan Zihan: Associate Chief Physician, clinical trial data collection, working time: 12 months.

Shao Jiashen: Resident Physician, data collection and sorting, working time: 12 months.

An Ning, Li Jiayi, Zhuang Haoxiang: Master students, data collection and sorting, working time: 18 months.

Zuo Weiyang: Master student, clinical benefit evaluation and data statistical analysis, working time: 18 months.