Endoscopic Discectomy with Repair of Annulus Fibrosus versus Discectomy Alone for Lumbar Disc Herniation: A Prospective Multicenter Randomized Controlled Trial

Study Protocol

Version Number: V1.0

Version Date: 2025-05-20

I. Research Background

(I) Current Status of Diagnosis and Treatment for Lumbar Disc Herniation

1. Lumbar Disc Herniation is not only a significant clinical issue but also a serious public health problem.

(1) Overview of Lumbar Disc Herniation Diagnosis and Treatment

Lumbar Disc Herniation refers to the protrusion of the nucleus pulposus through fissures in the annulus fibrosus, compressing adjacent neural tissues and causing symptoms such as low back pain, radiating leg pain, etc. This condition has a high incidence rate, affects a wide population, and severely impacts human health. According to reports in The Lancet, low back pain caused by lumbar disc herniation has become one of the leading causes of non-fatal health loss and is regarded as a serious public health problem.

The diagnosis of lumbar disc herniation is typically based on medical history, physical examination, imaging studies, and neurological examinations. Its main symptoms include: nerve compression symptoms, including low back pain; radiating leg pain; sensory disturbances such as numbness and tingling; muscle weakness, particularly foot drop in severe cases; and in cases of severe nerve root compression, difficulties with urination or defecation, among other clinical symptoms. Once the disease occurs, patients usually lose their ability to work.

Treatment for lumbar disc herniation primarily includes two categories: conservative treatment and surgical treatment. Non-surgical treatment (including lifestyle management, physical therapy, medication, etc.) is the first choice for patients with mild symptoms and short duration; for patients who do not respond to conservative treatment, surgical intervention may be considered based on their condition.

(2) The Incidence of Lumbar Disc Herniation Continues to Rise, with a Growing Young Patient Population

The incidence of lumbar disc herniation is positively correlated with age, being most prevalent in the 30-50 age group. The incidence among young and adolescent populations is lower than in middle-aged and elderly groups. According to 2015 statistics, the incidence rate of lumbar disc herniation in individuals under 45 years old was 0.65% to 3.7% [1]. However, recent epidemiological studies worldwide indicate a significant trend towards younger onset of lumbar disc herniation. With continuous changes in lifestyle, factors such as prolonged sitting, lack of exercise, and incorrect posture have led to a year-on-year increase in the incidence rate among adolescents [2, 3]. Other related factors include trauma, genetics and immunity, overweight or obesity, early disc degeneration, and developmental abnormalities [4-6].

According to data from the Seventh National Population Census, China's population aged 14-35 is approximately 400 million, accounting for 28.4% of the total population; the population aged 15-65 is 970 million, accounting for 66.55%. The combination of a large base of young and middle-aged and adolescent populations and continuously increasing incidence rate leads to a continuously rising number of lumbar disc herniation patients in this group. The loss of labor capacity in this population will inevitably have a significant negative impact on the economic growth, development, and stability of the entire society, undoubtedly warranting high attention.

3. Treatment Strategies and Advances for Lumbar Disc Herniation

The basic principle of treating lumbar disc herniation is the removal or ablation of the nucleus

pulposus to eliminate neural compression. However, past clinical technology development has primarily focused on middle-aged and elderly populations, failing to fully address the specific needs of young and adolescent patients for rapid recovery and minimizing impact on mobility.

① Regarding treatment efficacy, conservative treatment options are subject to some controversy.

On one hand, some studies suggest that the efficacy of conservative treatment in adolescent patients is not as satisfactory as in adults [7-9]. On the other hand, because conservative therapy often requires prolonged bed rest and is slow, during which normal learning and physical activities are almost impossible, it is not conducive to the physical, mental development, and character formation of adolescents.

② Among existing surgical methods, fusion surgery is not the preferred option.

Surgical treatment for lumbar disc herniation mainly includes fusion surgery and simple discectomy. Due to the younger age of young and middle-aged and adolescent populations, fusion surgery carries a higher risk of future adjacent segment disease [10] and is therefore not the preferred option.

③ Simple discectomy is the main recommended option, with endoscopic surgery holding the most advantages.

Traditional open discectomy, while capable of alleviating symptoms to some extent, has significant drawbacks: large trauma, high risk, slow recovery, numerous complications, and is prone to associated issues such as long-term chronic postoperative pain, extended recovery time, difficulty in complete restoration of lumbar function, and even iatrogenic loss of labor capacity [11, 12]. This reduces the quality of life for young patients and affects their future growth and development. Both patients and their families have significant concerns and are often reluctant to accept this type of procedure.

In contrast, minimally invasive spinal surgery techniques represented by spinal endoscopy in China have achieved major breakthroughs and rapid development in recent years. In treating diseases like lumbar disc herniation, lumbar spinal stenosis, and lumbar spondylolisthesis, they are now comparable to open surgery [13]. Endoscopic minimally invasive techniques have become one of the mainstream treatments for degenerative spinal diseases [14-19]. Furthermore, compared to traditional open surgery, minimally invasive surgery offers significant advantages such as minimal trauma, less impact on spinal stability, and shorter hospital stays, providing patients with safer and more effective treatment options, helping them quickly rid themselves of pain and return to normal life and activity levels [10, 20, 21].

④ Spinal Endoscopic Discectomy still faces critical issues that need urgent resolution.

While spinal endoscopic discectomy shows ideal short-term efficacy, like other treatments, it faces the hidden concern of postoperative recurrence. Existing clinical research data indicate a 5-year recurrence rate of 10-15% after lumbar discectomy, and a 9-year reoperation rate of up to 18.9% [22]. Additionally, although spinal endoscopic surgery is minimally invasive, it still inevitably causes disturbance to the perineural environment and can lead to postoperative scar adhesion, resulting in postoperative neurological symptoms such as paresthesia, affecting long-term postoperative quality.

Based on the above reasons, young and middle-aged and adolescent patients with lumbar disc herniation often struggle to receive timely, appropriate, and effective treatment, severely

impacting their physical and mental health and normal growth and development. Therefore, it is imperative to explore and develop more scientific treatment plans that quickly resolve the patient's pain, allowing them to return to normal study and life rhythms early, while also ensuring long-term efficacy and freeing patients from future worries.

(II) Current Existing Problems

1. Annulus Fibrosus Defect Post-Discectomy is a Significant Predisposing Factor for Recurrence of Disc Herniation

Besides factors such as severity of degeneration, local endplate inflammation, poor work and lifestyle habits, obesity, age, and inappropriate exercise, the annulus fibrosus defect following discectomy is a key predisposing factor for the **recurrence of disc herniation**.

Due to technical and equipment limitations, after removing the herniated nucleus pulposus tissue during discectomy, it is often impossible to simultaneously repair the rupture in the annulus fibrosus. Postoperatively, the annulus fibrosus is usually incomplete, with a local defect. The remaining nucleus pulposus within the disc continues to degenerate and may protrude again through the original annular rupture, compressing the nerve and causing symptom recurrence. A meta-analysis including 7 studies with 1653 patients who underwent lumbar discectomy, with an average follow-up of 2.9 years, included 499 cases with large annular defects (≥6mm) and 1154 cases with small defects. The results showed that compared to small defects, patients with large annular defects had significantly higher rates of symptomatic recurrence (OR=2.5) and reoperation (OR=2.3) [23]. Therefore, the annulus fibrosus defect after lumbar discectomy is an important factor affecting patient prognosis, and surgical repair of the annular rupture can play a positive preventive role in reducing postoperative recurrence to some extent.

2. Annulus Fibrosus Suture Technology is a Feasible Option for Repairing Annular Defects, but has Not Been Fully Developed.

(1) The application effect of annulus fibrosus suture technology in **cases of traditional open discectomy is extremely limited, but its potential application value is undeniable.**

Annulus fibrosus suture technology was first reported by Professor Gazi Yasargil of the University of Zurich in 1977 [24]. It was initially applied in open surgery. Due to the large surgical wound and wide exposure, which caused severe damage to the perineural environment, extensive adhesions often occurred postoperatively. Even with the application of annular repair technology, it was almost "a drop in the bucket," offering no significant benefit to the prognosis [25]. Consequently, this technology was shelved for a long time, but its potential application value has still been unanimously recognized by researchers.

(2) The Annulus Fibrosus Defect Caused by Spinal Endoscopic Discectomy is More Likely to be Repaired by Annulus Fibrosus Suture Technology**, but Related Research is Insufficient.**

In the case of spinal endoscopic surgery, during the removal of the herniated nucleus pulposus tissue, the locally bulging annulus fibrosus is often removed as part of the herniation, resulting in defects of varying degrees. In the short term, the annular defect loses its barrier function and is the main physical factor for early recurrence after disc herniation surgery. Subsequently, although the defect can gradually be filled with scar tissue, it still forms a weak area. Since adolescents are typically more active than adults, this weak area becomes a hidden risk for medium- to long-term recurrence [22, 26]. Moreover, during the process of scar tissue

formation and filling of the defect at the annulotomy site, it inevitably forms adhesions to varying degrees with adjacent neural tissues, causing varied manifestations of neurological dysfunction, especially different types of paresthesia, which affect the patient's postoperative quality of life.

Additionally, the lumbar disc annulus fibrosus and the overlying posterior longitudinal ligament are tough and smooth, with a potential space dorsally, creating a comfortable natural environment for the adjacent dural sac and nerve roots. During disc surgery, inevitable nerve traction, electrocautery for hemostasis, incision or even resection of part of the annulus fibrosus and posterior longitudinal ligament, coupled with postoperative organization of hematoma and scar formation, severely disrupt the normal surrounding environment of the neural tissues, exacerbating paresthesia in the areas innervated by those nerves postoperatively.

Therefore, scientifically determining the extent of annulotomy and achieving endoscopic annular repair is of great significance for the treatment of lumbar disc herniation. However, this vision has not yet been fully realized.

(III) Domestic and International Research Progress

Based on the foregoing, it can be inferred that if the original context of annulus fibrosus suture technology can be transformed, adapting it for application in spinal endoscopic surgery, successfully combining the "minimally invasive" and "repair" pillars to stack advantages, it will undoubtedly achieve a significant leap in preventing recurrence of disc herniation.

In stark contrast to the stagnation in international research in this field, this idea has been actively implemented and pioneered by scholars and domestic companies in China in this field. After ten years of arduous exploration, a domestically developed, world-first spinal endoscopic annulus fibrosus suture device and its supporting tools were successfully launched in 2019. Using this instrument, the delicate action of suturing the annulus fibrosus can be completed within the endoscopic channel, achieving the goal of successfully performing annulus fibrosus suture repair under spinal endoscopy, opening a new era in spinal endoscopic technology. This set of purely domestic, original research tools and technology with complete independent intellectual property rights is another representative achievement of the integration of industry, academia, research, and medicine in China's spinal minimally invasive field, occupying an internationally leading position.

(IV) Regarding the Research Content of This Project

Practice has shown that the application of spinal endoscopic annulus fibrosus suture technology can promote primary closure of the annular rupture, creating conditions for its rapid repair, thereby effectively reducing the early recurrence rate of disc herniation [27]. Furthermore, primary closure of the rupture and rapid annular repair also have the following important roles: ① It restores the integrity of the annulus fibrosus, greatly reduces the formation of local scar tissue, better reconstructs the natural environment of the nerve root and dural sac, significantly reduces nerve adhesion, eliminates paresthesia in the area innervated by the nerve root after endoscopic surgery, and improves patient postoperative comfort and long-term quality of life. ② It effectively prevents the leakage of inflammatory mediators from within the disc, helping to reduce the inflammatory response in adjacent neural tissues, and can better eliminate early postoperative neurological symptoms in patients [28]. ③ It creates favorable conditions for the future implementation of biological treatments

for disc degeneration and tissue engineering techniques [29, 30].

Thus, the 诞生 (birth) and application of spinal endoscopic annulus fibrosus repair technology can not only effectively solve the current clinical dilemma but also lay the technical foundation for a new scenario combining surgical and biological treatments for disc degeneration in the future. According to statistics, since the sixth-generation annulus suture device was put into clinical use two years ago, approximately 12,000 spinal endoscopic annulus suture surgeries have been completed nationwide, with an average suture time of 8 minutes. This means that the application of this technology extends the spinal endoscopic surgery time by less than 10%, yet allows patients to obtain huge therapeutic benefits. This set of purely domestic, original research tools and technology with complete independent intellectual property rights is another representative achievement of the integration of industry, academia, research, and medicine in China's spinal minimally invasive field, occupying an internationally leading position.

In summary, spinal endoscopic annulus fibrosus suture technology holds significant value for the treatment of lumbar disc herniation, mainly reflected in: ① achieving a minimally invasive solution, avoiding iatrogenic injury associated with open surgery; ② greatly reducing the risk of short-term recurrence, enabling patients to return to normal study, life, and sports more quickly; ③ restoring homeostasis in the spinal canal environment, eliminating early postoperative neurological symptoms, and achieving better treatment outcomes.

Based on the above progress, this study aims to further explore the surgical indications, summarize technical key points, identify directions for improvement, and investigate the clinical efficacy and recurrence prevention effects of minimally invasive spinal annulus fibrosus suture surgery through a prospective multicenter randomized controlled trial. It seeks to provide objective data support for this promising key technology and continuously enhance the standardization and scientific level of its clinical application.

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II. Research Objectives and Significance

(I) Research Objectives:

Through this large-sample, multicenter randomized controlled trial, to explore the safety and clinical efficacy of spinal endoscopic discectomy combined with annulus fibrosus repair technology in the treatment of lumbar disc herniation, specifically including the following aspects:

1. Evaluate the effectiveness of the annulus fibrosus suture technique, clarifying whether it can significantly reduce the postoperative recurrence rate of disc herniation.
2. Assess the safety of the annulus fibrosus suture technique, comparing differences between the suture group and the control group in terms of perioperative complications and the risk of early postoperative pain exacerbation.

(II) Research Significance:

Addressing the caution exercised by lumbar disc herniation patients and their families in selecting surgical options and their expectations for surgical outcomes, this study aims to explore the surgical indications for spinal endoscopic annulus fibrosus suture surgery, summarize technical key points, and investigate its clinical efficacy and recurrence prevention effects through objective multicenter clinical research data. It seeks to provide supporting data for this highly promising future technology and offer supporting experience for the broad patient population and medical peers.

Clinical Application Research: Systematically evaluate the feasibility and effectiveness of spinal endoscopic annulus fibrosus suture surgery in treating lumbar disc herniation, focusing on analyzing its efficacy and safety.

Technical Advantages and Challenges: Discuss the advantages of spinal endoscopic technology compared to traditional open surgery, such as minimal surgical trauma, rapid recovery, and fewer complications, particularly its applicability and limitations in managing disc problems in adolescents.

III. Research Content and Technical Route

(1) Study Type

A Prospective Multicenter Randomized Controlled Trial on Endoscopic Discectomy Combined with Annulus Fibrosus Repair Technology for Lumbar Disc Herniation

Study Type: Prospective, Multicenter, Randomized Controlled Trial.

(2) Study Population

- **Recruitment Target:**
  The study population consists of patients with lumbar disc herniation who are normally admitted and charged at multiple research centers and have indications for surgical treatment.
- **Recruitment Methods**
  1. Post recruitment notices in outpatient or specialist clinics, clearly stating the study's purpose, inclusion criteria, exclusion criteria, contact information, etc.
  2. Conduct universal screening of all visiting patients and invite eligible patients to participate in the study based on screening results.
  3. Utilize existing patient registries to screen for and recruit eligible subjects.
- **Inclusion Criteria:**
  1. Age between 12 and 65 years, inclusive, regardless of gender;
  2. Diagnosed with lumbar disc herniation;
  3. Herniation type is non-calcified;
  4. Preoperative disc MRI shows Pfirrmann grade I-II;
  5. Ineffective after conservative treatment for 6 months or more, with symptoms significantly affecting quality of life;
  6. Able to cooperate with long-term follow-up and sign the informed consent form.
- **Exclusion Criteria:**
  1. Accompanied by lumbar spondylolisthesis, lumbar instability, or other lumbar diseases;
  2. History of previous lumbar surgery;
  3. Comorbidities with other major systemic diseases, unable to tolerate surgery;
  4. Diseases that may affect postoperative progress, such as malnutrition, bone metabolism abnormalities, autoimmune diseases, etc.;
  5. Unable to undergo regular follow-up.
- **Termination Criteria:**
  1. Occurrence of severe complications during surgery preventing its continuation;
  2. Changes in condition during the treatment process preventing the surgical plan from proceeding as intended;
- **Withdrawal Criteria:**
  1. Failure to complete all processes specified in the clinical trial after enrollment;
  2. Loss to follow-up for various reasons;
  3. Non-compliance with the research plan requirements, such as not following doctor's orders, failing to receive treatment or follow-up on time;
  4. Request to withdraw due to adverse reactions.

(3) Research Methods

1. Trial Process

- **Study Groups:**
  1. Annulus Fibrosus Suture Group
  2. Non-Annulus Fibrosus Suture Group
- **Center Preparation**

This center will provide specialized training to researchers on the standard operating procedures for annulus fibrosus suture surgery and the data management system. Submit ethics application and obtain approval, ensuring the study meets ethical requirements.

- **Subject Recruitment and Screening**

Recruit patients diagnosed with lumbar disc herniation aged between 12 and 65 years, ensuring they meet the inclusion criteria and sign the informed consent form. Conduct detailed medical history inquiry, physical examination, and neurological examination for subjects, and complete various preoperative tests.

- **Surgery Implementation**

Perform the corresponding surgical treatment based on the patient's condition, and assign groups (Annulus Fibrosus Suture Group and Non-Suture Group) according to randomization. The entire surgical procedure will be recorded on video to ensure standardized operation.

- **Postoperative Follow-up**

Patients will return to the research center for follow-up assessments after surgery to evaluate pain relief, functional recovery, and occurrence of complications.

Follow-up time points include 1 month, 3 months, 6 months, and 1 year postoperatively, with at least one follow-up conducted.

- **Data Collection and Analysis**

Collect and organize patient preoperative, intraoperative, and postoperative data, including pain scores, disability indices, imaging data, etc. Perform statistical analysis on the data to evaluate the effectiveness, efficacy, and safety of spinal endoscopic annulus fibrosus suture surgery.

- **Randomization Method**

If a patient meets the enrollment criteria for this study, PASS 11.0 random list will be used for randomization. After the patient provides written informed consent, completes necessary baseline assessments, and the research physician confirms eligibility, the patient will be assigned to the corresponding group on the random list according to the order of admission.

2. Statistical Analysis Methods

(1) Statistical Software, Statistical Standards

Data Collection: Use an Electronic Data Capture (EDC) system to collect clinical data and patient-reported outcome measures.

Data Management: Ensure data integrity, accuracy, and confidentiality. Conduct regular quality control and supervision to ensure standardized and systematic data entry and management. Data entry will be performed by specially trained research personnel, and data validation rules will be set in the system to ensure accuracy and consistency.

Statistical Software: Use SPSS 25.0 software for Windows (IBM Co, Armonk, NY, USA) for statistical analysis.

Repeated Measures Data: Comparison of repeated measures data will be performed using repeated measures analysis of variance.

Missing Data Handling: Appropriate missing data imputation methods will be used based on the characteristics of the missing data. Sensitivity analysis will be conducted for missing data during the research process.

Data Integrity and Accuracy: The study coordinator and data management team will regularly review data entry, promptly identifying and correcting errors. Establish a data quality control

plan, including double data entry, random sampling checks, etc., to ensure high data quality. Systematically train researchers involved in data collection and management, and conduct regular supervision and evaluation to ensure they understand and strictly follow data management procedures.

Data Confidentiality: Use unique study identification numbers instead of patient personal information to ensure privacy protection. Employ data encryption techniques to ensure data security during transmission and storage. Set strict access permissions so that only authorized personnel can access and process data. Perform regular data backups to prevent data loss. Develop a detailed disaster recovery plan to ensure rapid data recovery in case of data loss or system failure.

(2) Statistical Methods

All statistical descriptions will use appropriate forms for expressing measurement data and count data.

Statistical Description: Continuous variables such as operation time, blood loss, etc., will be tested for normality using the Kolmogorov-Smirnov test. Measurement data conforming to normal distribution will be expressed as mean ± standard deviation, while non-normally distributed data will be expressed as median (interquartile range). Count data will be expressed as frequency (percentage).

Difference Comparison: T-tests will be used for comparisons between two groups for normally distributed data, analysis of variance (ANOVA) for comparisons among multiple groups, and the Mann-Whitney U test for non-normally distributed data. Chi-square tests will be used for comparisons between groups for count data. Specifically, for the primary outcome measure of recurrence rate, chi-square test will be used for difference testing.

Primary Outcome Measure Comparison: Particularly for the primary outcome measure such as recurrence rate, chi-square test will be used for intergroup comparison to assess differences under different treatment schemes or research conditions.

Repeated Measures Data Analysis: For data with time series or repeated measurements, Repeated Measures ANOVA will be used to compare trends over different time points or under different treatment conditions.

Missing Data Handling: Based on the characteristics and distribution of missing data, appropriate imputation methods will be used to ensure the completeness and accuracy of the analysis. Sensitivity analysis will be conducted for missing data during the research process to assess its impact on the study conclusions.

(4) Research Content and Indicators

1. **Evaluation Indicators**

   Primary Indicators

   1. Surgical Success Rate: The proportion of surgeries where the annulus fibrosus suture was successfully completed.
   2. Recurrence Rate: The proportion of patients experiencing re-herniation at the operated segment within a certain period postoperatively, including short-term and long-term recurrence.
   3. Postoperative Efficacy: Assess improvement in patient quality of life using VAS (low back pain, leg pain) scores, lumbar JOA score, and ODI index.
   4. Reoperation Rate: The proportion of patients requiring reoperation due to

surgical failure, short-term postoperative recurrence, or postoperative complications.

5. Postoperative Inflammatory Indicators: Patient postoperative blood routine, CRP, procalcitonin, and other inflammatory markers.

Secondary Indicators

6. Nerve Injury: The proportion of postoperative nerve injuries, including sensory and motor nerve damage.
7. Bleeding and Hematoma: The proportion of postoperative bleeding and hematoma occurrences, assessing vascular and soft tissue damage during surgery.
8. Complication Rate: The proportion of various intraoperative and postoperative complications, such as infection, dural leakage, etc.
9. Postoperative Infection Rate: The proportion of patients developing postoperative infection, including superficial and deep infections.

2. **Observation Content**
    1. **Patient Demographic Data:** Gender, age, BMI, etc.;
    2. **Perioperative Parameters:** Surgical level, operation time, blood loss, hospital stay, postoperative complications, etc.;
    3. **Clinical Efficacy Assessment:** VAS scores, ODI index, lumbar JOA score;
    4. **Imaging Data:** Disc herniation area, size of annulus fibrosus rupture, spinal canal area preoperatively, postoperatively, and at various follow-up stages, etc.;
    5. **Laboratory Indicators:** Blood routine, CRP, procalcitonin, IL-6, etc.;
    6. **Occurrence of Clinical Events:** Whether the suture was successful, whether recurrence occurred, whether infection occurred, whether complications such as nerve injury occurred, etc.

The treatment period involves regular follow-up assessments preoperatively, and at 1 month, 3 months, 6 months, and 12 months postoperatively. Assessment includes evaluation of pain scores, disability indices, recurrence rate, complications, and other indicators. MRI review will be conducted at 3 months postoperatively, CT review at 6 months postoperatively, and CT and MRI review at 1 year postoperatively.

(5) Follow-up Schedule

Stage / Data Category		Baseline Period	Perioperative Period	Follow-up Period			
Timeline		-10 ~ 0 days	0 (Surgery)	Postop 1M	Postop 3M	Postop 6M	Postop 12M
Basic Information	Demographics	√					

	Present Illness	√					
	Past History	√					
nclusion/Exclusion Criteria	Surgical History	√					
	Herniation Type	√					
	Disc MRI Grade	√					
	Nutrition Score	√					
	Blood Biochemistry	√					
	Other Special Circumstances	√					
Imaging Studies	DR	√					
	CT	√				√	
	MRI	√			√		√
Observation Indicators	Perioperative Params		√				
	Clinical Efficacy Scores	√		√	√	√	√
	Inflammatory Markers	√	√				
	Suture Success		√				

	Complications		√	√			
	Recurrence			√	√	√	√

(6) Study Scale

1. **Total Study Scale**

   Based on literature review, the baseline overall recurrence rate after current spinal endoscopic surgery is 5%. It is estimated that under the spinal endoscopic annulus fibrosus suture mode, the postoperative recurrence rate will decrease to 2.4%. Setting two-sided α = 0.05 and power at 90%, according to the sample size formula:

   $$n = \frac{2 \times (Z_{1-\alpha/2} + Z_{Power})^2 \times (p1 \times (1-p1) + p2 \times (1-p2))}{(p1-p2)^2}$$

   The calculated sample size should be 224 cases. The total sample size is set at 300 cases to accommodate a possible 20% dropout rate and minimize errors attributable to sample size.

2. **Scale for This Unit**

   Based on comprehensive evaluation of this unit's surgical volume, human resources, and capacity, the research scale is set at 100 cases.

(7) Multicenter Research Units

The First Affiliated Hospital of Harbin Medical University

Shengjing Hospital of China Medical University

Liaoning Provincial People's Hospital

The Second Affiliated Hospital of Dalian Medical University

Shandong Provincial Hospital Affiliated to Shandong First Medical University

The Affiliated Hospital of Qingdao University

Qilu Hospital of Shandong University

The First Affiliated Hospital of Shandong First Medical University

Jiangsu Province Hospital of Traditional Chinese Medicine

The Fourth Affiliated Hospital of Zhejiang University School of Medicine

The First Affiliated Hospital of Wenzhou Medical University

Peking Union Medical College Hospital

The First Affiliated Hospital of Harbin Medical University

Beijing Hospital

Xuanwu Hospital, Capital Medical University

The First Affiliated Hospital of Xinxiang Medical University

Shanxi Provincial People's Hospital

The Second Hospital of Shanxi Medical University

The Second Affiliated Hospital of Bengbu Medical University

Hubei Provincial People's Hospital

Wuchang Hospital of Wuhan

The Third Xiangya Hospital of Central South University

The First Affiliated Hospital of Nanchang University

The Affiliated Hospital of Jiujiang University

The Second Affiliated Hospital of Xi'an Jiaotong University

Tongren Hospital, Shanghai Jiao Tong University School of Medicine

Shenzhen Hospital of Southern Medical University

The Second Affiliated Hospital of Guangzhou Medical University

Shenzhen Second People's Hospital

The People's Hospital of Guangxi Zhuang Autonomous Region

Hainan Provincial People's Hospital

Qujing First People's Hospital

The First Affiliated Hospital of Kunming Medical University

Yunnan Provincial Hospital of Traditional Chinese Medicine

The First Affiliated Hospital of Harbin Medical University

Kunming Orthopedic Hospital

The Affiliated Hospital of Southwest Medical University

The Affiliated Hospital of Chengdu University of Traditional Chinese Medicine

Yongchuan Hospital of Chongqing Medical University