ABSTRACT

Introduction  To improve the efficacy of anterior cervical decompression and fusion (ACDF) and reduce postoperative complications in degenerative cervical myelopathy, our team established a set of perioperative care of enhanced recovery guidelines of ACDF based on the concept of enhanced recovery after surgery. In addition, a prospective, multicentre, randomised clinical trial was designed.

Methods and analysis  A total of 260 patients aged 18–65 years will be included. Preoperative MRI and CT will be used to confirm the typical manifestations of cervical spondylosis, such as cervical disc herniation and spinal cord compression. The patient presents with neck and shoulder pain, numbness of upper limbs, weakened grip strength and cotton sense of foot tread. Patients received normal conservative treatment for 3 months with no obvious relief or even aggravation of symptoms. Patients will be assigned to the group in strict accordance with the random allocation table. Patients in groups A and B will receive conventional perioperative care and perioperative care for enhanced recovery, respectively. The main outcome indicators are the Kamolfsky Performance Scale score and the Japanese Orthopaedic Association scale. Secondary outcome indicators are pain assessment by Numeric Rating Scale, Neck Disability Index, quality of life index (QL-Index) and postoperative complications. Follow-up will be conducted at 3, 6 and 12 months postoperatively.

Ethics and dissemination  Ethical approval has been granted by the Ethics Committee of Fujian Medical University Union Hospital, Fuzhou, China (2020YF034-01). Results of the research will be published in an international peer-reviewed scientific journal and disseminated through presentation at scientific conferences.

Trial registration number  ChiCTR2000040508.

INTRODUCTION

Degenerative cervical myelopathy (DCM) is caused by direct compression of the spinal cord or inadequate local blood supply to the spinal cord. A significant aetiology is cervical stenosis as it can be congenital or mostly secondary stenoses. Disc herniation, ligamentum flavum folding and osteophytes can all result in reduced cervical canal space. DCM is causing progressive disability and affecting the quality of life. The characteristic symptoms and signs of DCM include loss of flexibility of the hand, decreased muscle strength, stiffness of the limbs, urination urgency, frequency or hesitation of urination, limb spasm and gait disorder (including stiff or spastic gait). The conservative treatment of DCM usually includes neck support bracing, analgesic drugs, epidural hormone injection, nerve root block, facet joint closure, facet joint drenching. Traction and massage may cause further compression of the spinal cord, so it should be prohibited. Progression of neurological dysfunction and changes in spinal cord signals on T2-weighted MRI are clear indications for surgery. The purpose of the procedure is to relieve the compression of the spinal cord and restore the normal curvature of the cervical spine.

Smith and Robinson described anterior cervical decompression and fusion (ACDF)
in 1958. This surgical approach is still the standard surgical approach for the treatment of cervical disc herniation. Anterior cervical surgery, through extensive removal of the disc, can directly decompress the spinal cord and bilateral nerve roots, as well as facilitate the implantation of artificial discs or other artificial fusion materials. First proposed by Henrik Kehlet in 1997, the enhanced recovery after surgery (ERAS) is a series of perioperative optimisation measures based on evidence-based medicine to reduce the physiological and psychological traumatic stress during perioperative period, reduce complications and accelerate recovery. This is a multidisciplinary, multimodal approach. ERAS has been successfully applied in general surgery, cardiothoracic surgery, obstetrics and gynaecology, orthopaedic joint replacement surgery and other fields. In recent years, it has been gradually developed in the field of spinal surgery and accepted by more spinal surgeons. Although the treatment of DCM with ACDF has the advantages of small incision and surgical trauma, the incision is adjacent to important nerve vessels, and the tissue structure is complex, thus posing certain surgical risks and surgical complications. In addition, postoperative complications such as hoarseness and swallowing discomfort are often caused by intraoperative tractive trachea and implantation of plate internal fixation materials. To improve the efficacy of ACDF and reduce postoperative complications, the team established a set of perioperative care of enhanced recovery (PCER) guidelines of ACDF based on the concept of ERAS. PCER is designed to increase the perioperative nutrition intervention, preoperative intervention of early rehabilitation training, intraoperative strengthening of heat preservation, postoperative change of routine rehabilitation training mode, such as increasing the use of rehabilitation training equipment, self-made training exercises, etc., in order to promote the rapid recovery of patients after surgery, to achieve satisfactory nursing efficacy. The arising amount of data showing that the use of ERAS programmes could be helpful in reducing the days of hospitalisations and the number of complications for cervical spine surgery in a highly selected group of patients also highlight the current lack of high level of scientific evidence. Therefore, a prospective, multicentre, randomised clinical trial has been designed, in which patients receiving ACDF will be randomly divided into two groups and PCER and conventional perioperative care (CPC) will be applied to explore the nursing effect of PCER in patients receiving ACDF treatment.

**METHODS AND ANALYSIS**

**Study description**

This study is a prospective, multicentre, non-inferiority randomised controlled trial (RCT) to compare the nursing effect difference between CPC and PCER for patients treated with ACDF. The follow-up period will continue for 1 year. The actual intervention will be concealed from the subjects and follow-up researchers until the end of the follow-up period. The main assessment indicators are Karnofsky Performance Scale (KPS) score and Japanese Orthopaedic Association (JOA) score. Table 1 shows the time points of screening, randomisation and evaluation in detail.

**Participant recruitment and eligibility**

The participant will be conducted on a voluntary basis, so only after each appropriate patient agrees to participate and

| Table 1 Flow chart visits and case report forms |
|------------------------------------------------|
| **Time for evaluation** | **Screening period** | **Intervention period** | **Evaluation period 1** | **Evaluation period 2** | **Evaluation period 3** | **Evaluation period 4** |
|-------------------------|---------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| Assessment              | Screen              | Randomisation          | Hospital discharge     | 3 months following treatment | 6 months following treatment | 12 months following treatment |
| Eligibility screen      | ✓                   | ✓                      |                         |                        |                        |                        |
| Informed consent        | ✓                   | ✓                      |                         |                        |                        |                        |
| Demographic information | ✓                   | ✓                      |                         |                        |                        |                        |
| Admission health education | ✓                  | ✓                      |                         |                        |                        |                        |
| Auxiliary inspection guide | ✓                  | ✓                      | ✓                      | ✓                      | ✓                      | ✓                      |
| Preoperative guidance   | ✓                   | ✓                      |                         |                        |                        |                        |
| Intraoperative care     | ✓                   | ✓                      |                         |                        |                        |                        |
| Postoperative nursing   | ✓                   | ✓                      |                         |                        |                        |                        |
| Nursing document writing | ✓                  | ✓                      |                         |                        |                        |                        |
| Occurrence of complications | ✓                 | ✓                      | ✓                      | ✓                      | ✓                      | ✓                      |
| Discharge guidance      | ✓                   | ✓                      |                         |                        |                        |                        |
| Nursing adverse events  | ✓                   | ✓                      |                         |                        |                        |                        |
| Cervical functional assessment | ✓               | ✓                      | ✓                      | ✓                      | ✓                      | ✓                      |
signs the informed consent, they will be placed on the waiting list. Detailed inclusion and exclusion criteria are as follows.

**Inclusion criteria**
1. Aged 18–65 years.
2. Preoperative MRI and CT confirmed signs of cervical disc herniation and compression of spinal cord.
3. Typical manifestations of cervical spondylosis, such as neck and shoulder pain, numbness of both upper limbs, weakened grip strength and cotton feeling on the feet.
4. Normal conservative treatment for 3 months, no obvious relief or even worse symptoms.
5. No absolute surgical contraindication.
6. Informed and consented.

**Exclusion criteria**
1. With a history of cervical spine surgery.
2. Congenital spinal stenosis or cervical deformity.
3. With dysphagia before surgery.
4. With infection and tumour.
5. Expected survival time is less than 1 year.
6. With language communication disorder.
7. Participating in other clinical trials.
8. With rheumatic immune diseases that may cause similar symptoms.
9. Not suitable for MRI, CT and other special examinations.

**Patient and public involvement statement**
The patients and the public were not (or will not) be involved in the design, or conduct, or reporting or dissemination of the research.

**Randomisation and blinding**
A completely randomised scheme will be used in this study. After signing the written consent, the randomisation specialist will import the patient information into the EDC system after the patient’s enrolment is confirmed by the enrolment specialist. The EDC system will randomly assign the patients to PCER or CPC, and the random results will be sent to the designated mailbox. The responsible nurses will provide perioperative nursing according to the assigned results. A double-blinded design will be used in this study, for follow-up specialists and statistical specialists as well as for patients and research assistants. However, the responsible nurse has the right to know about the grouping of patients.

**Interventions**
Patients will be randomly assigned to the CPC and PCER groups. The common treatment measures for the two groups from admission to follow-up are as follows.
1. Health education on admission: the introduction of the chief physician and the responsible nurse; guidance on the environment, facilities and safety management of wards and advice on quitting smoking and drinking.

2. Guidance on matters requiring attention during the preoperative examination.
3. Perioperative assessment: routine nursing risk assessment, including assessment of nutritional status (NRS2002 table), inpatient fall bed/fall risk assessment, pressure ulcer risk assessment (Braden scale), thrombosis risk assessment (Caprini scale), the function of daily life activities condition assessment (Barthel table), sleep assessment (PSQI scale) and pain assessment (Numeric Rating Scale, NRS), Quality of Life Index (QL-index). Specialist spine assessment: cervical spine dysfunction assessment (Neck Disability Index, NDI scale); neck muscle strength assessment: freehand muscle strength test (MTT), neck range of motion measurement, JOA score, KPS score, etc.
4. Preoperative preparation: cervical overextension training and guidance for the wearing of a neck brace, the handling of personal hygiene, the preparation of effective cough and sputum, and the preparation of necessary surgical items.
5. All patients will undergo ACDF under general anaesthesia.
6. Intraoperative nursing: the temperature between operations should be kept at 25°C; the patient’s body temperature will be monitored at the beginning and after the operation and catheterisation will be performed after general anaesthesia.
7. Postoperative care: the patients will be given grade I care, ECG monitoring and low-flow oxygen inhalation when they return to the ward on the day of operation. The respiratory tract will be kept unblocked and we will closely observe the changes in the patient’s respiratory frequency and rhythm. Oozing fluid at the incision sight will be monitored; medical treatment will be given as advised.
8. Discharge: the patients will be given diet guidance, rest and activity guidance, discharge medication guidance, return visit guidance and rehabilitation exercise guidance.
9. Follow-up: follow-up will be conducted at 3, 6 and 12 months after surgery, including cervical spine dysfunction assessment (NDI scale), cervical mobility measurement, JOA cervical spine score, KPS functional status assessment and life quality score (QL-index) to understand the incidence of complications.

Patients in CPC group and PCER group received different nursing programmes, as shown in the table 2.

**Baseline assessment**
Baseline records will include demographic, admission diagnosis, admission time, operation time, discharge time, postoperative length of stay, cost, etc.

**Outcomes assessment**
The following validated outcome measures will be used in the form of a questionnaire to evaluate the efficacy of nursing care.
| Time                  | CPC group                                                  | PCER group                                                  |
|----------------------|------------------------------------------------------------|-------------------------------------------------------------|
| **On admission**     | Admission health education /                              | Admission health education /                                |
|                      | Pelvic floor muscle training (levator anal training)       |                                                             |
|                      | Diet                                                       | Diet                                                        |
|                      | □Regular diet                                              | □Healthy diet; high in protein and coarse fibre; low in fat; avoid spicy irritation |
|                      | Psychological assessment /                                 | Psychological assessment /                                  |
|                      | □Assessed by SAS scale                                     |                                                             |
| **Preoperative day** | Oral care                                                  | Oral care                                                   |
|                      | □Brush teeth (using a toothbrush)                           | □Brush teeth (using a toothbrush)+ gargle (ciprofloxacin chloride gargle) |
|                      | Protect lung intervention /                                | Protect lung intervention /                                 |
|                      | □Guidance on deep breathing and cough effectively /        | □Breath trainer machine /                                   |
|                      | □Guidance on deep breathing and cough effectively           | □Atomisation two times per day or three times a day          |
|                      | Preoperative rehabilitation training guidance /            | Preoperative rehabilitation training guidance /             |
|                      | □Position training: neck overextension /                    | □Position training: neck overextension +axis turn /          |
|                      | □Position training: neck overextension                      | □Trachea push–pull training /                               |
|                      | □Regular diet                                              | □One day before surgery, choose the diet according to the diet provided |
|                      | □No food or drink after 22 o’clock                         | □800 mL of 12.5% carbohydrate was taken oral administration 12–13 hours before surgery |
|                      | □No food or drink after 22 o’clock                         | □400 mL of 12.5% carbohydrate was taken oral administration 2–3 hours before surgery |
| **In the operation** | Intraoperative insulation /                                | Intraoperative insulation /                                 |
|                      | □Room temperature 25°C                                      | □Room temperature 25°C+insulation blanket                   |
| **On the day of surgery** | Diet                                                      | Diet                                                        |
|                      | □Fasting                                                   | □400 mL of 12.5% carbohydrate was taken oral administration 6 hours after surgery |
|                      | Position guidance                                          | Position guidance                                           |
|                      | □Fix both sides of neck with sandbags                      | □Neck limiter                                               |
|                      | Pain management                                            | Pain management                                             |
|                      | □Use painkillers when the patient is in pain               | □Use of non-steroidal analgesics (carmine)                  |
|                      | Oral care                                                  | Oral care                                                   |
|                      | □Gargle with warm water                                    | □Gargle with ciprofloxacin chloride gargle                   |

Continued
Table 2  Continued

| Time                                      | CPC group                                                                 | PCER group                                                                 |
|-------------------------------------------|---------------------------------------------------------------------------|---------------------------------------------------------------------------|
| The first day after surgery—the day before discharge | Diet  
  ☐Transition from liquid to normal diet.  
  ☐Position guidance  
  ☐Fix both sides of neck with sandbags  
  ☐Oral care  
  ☐Brush teeth (using a toothbrush)  
  ☐Breathing training  
  ☐Guidance on deep breathing and cough effectively  
  ☐Time to get out of bed  
  ☐Proceed according to actual situation  
  ☐Catheter removal time  
  ☐Proceed according to actual situation  
  ☐Rehabilitation exercise  
  ☐Prevention of VTE  
  ☐Active activities of upper limbs  
  ☐Bedside activities  
  ☐The wound  
  ☐Use infrared irradiation when poor healing occurs | Diet  
  ☐Nutritional powder was taken on the first day after surgery, and then a normal diet was transitioned  
  ☐Position guidance  
  ☐Neck limiter  
  ☐Oral care  
  ☐Brush teeth (using a toothbrush)+gargle (ciprofloxacin)  
  ☐Breathing training  
  ☐Breath trainer machine  
  ☐Time to get out of bed  
  ☐48 hours later (the second day after surgery)  
  ☐Psychological support and encouragement for getting out of bed  
  ☐Catheter removal time  
  ☐24 hours after surgery  
  ☐Rehabilitation exercise  
  ☐Prevention of VTE: use mini lower extremity trainer  
  ☐Neck muscle relaxation  
  ☐Thermal application of trapezius (infrared radiation) and massage  
  ☐The wound  
  ☐Infrared radiation (from the first day after surgery) |

CPC, conventional perioperative care; PCER, perioperative care of enhanced recovery; SAS, Social Anxiety Scale; VTE, Venous Thrombus Embolism.
Primary outcome measures

1. Karnofsky score (KPS)\textsuperscript{16}

The higher the KPS score, the better the health, the more tolerable the side effects of the treatment, and therefore, the more likely the patient is to undergo thorough treatment. It is generally believed that a KPS score above 80 is independent, that is, independent in daily living. A score of 50–70 is classified as semi-independent, that is, semi-independent living. A score below 50 is dependent.

2. Japanese Orthopaedic Association (JOA)\textsuperscript{17,18}

The JOA scale will be used to assess neurological function. JOA scores at admission, after surgery, before discharge and during follow-up will be recorded. The full score is 17, and the postoperative improvement rate will be calculated as follows: \((\text{postoperative total score–preoperative total score})/17\times100\%\); improvement rate \(\geq 25\%\), excellent; \(50\%–74\%\), good; \(25\%–49\%\), medium; \(0\%–24\%\), poor.

Secondary outcome measures

1. Numeric Rating Scale (NRS)\textsuperscript{19}

Pain assessment with the NRS: 0–10 is used to represent different degrees of pain in the numeric rating method. The pain rating standard is 0, painless; 1–3, mild pain; 4–6, moderate pain; 7–10, severe pain.

2. Neck Disability Index (NDI)\textsuperscript{20}

NDI is commonly used clinically to assess the cervical spine functional status. The scale includes 10 aspects: pain, personal care, lifting, reading, headache, attention, work, driving, sleep and recreation. Each item is five points and the score ranges from 0 (barrier-free) to 50 (complete paralysis); the higher the score, the worse the dysfunction. Cervical spine functional impairment index (%): \((\text{total score per project/number of completed projects}\times5)\times100\%\). The results were 0%–20%, indicating mild dysfunction; 20%–40%, indicating moderate dysfunction; 40%–60%, severe dysfunction; 60%–80%, very severe dysfunction and 80%–100%, complete dysfunction or should be carefully checked for exaggerated symptoms.

3. Quality of Life Index (QL-Index)\textsuperscript{21}

QL-Index, designed by Spitzer in 1981, is a simple scale that can quickly evaluate patients’ quality of life and help estimate the treatment effect of severe diseases and the degree of disease alleviation. The scale consists of five aspects: activity, daily life, health, support and general situation, with three levels of 0.1.2 for each item. Choose the most appropriate column item by item according to the patient’s current situation, and record the corresponding score. QL-Index=Activity Score +Daily Life Score +Health Score +Support Score +General Situation Score. The total score ranged from 0 to 10, with a high score of 10 and a low score of 0. Those with high scores had a better quality of life than those with low scores; 0–3 was a very low score. The best was a trend analysis: an increase in scores suggested improvements in quality of life. Decreased scores indicate a deterioration in quality of life.

4. Postoperative complications

There are two main types of postoperative complications. Early surgical postoperative complications including surgical haematoma; tissue swelling; dural tear/CSF leakage; voice hoarseness/difficulty swallowing; nerve root palsy (transient/permanent); injury to vascular structures, trachea, oesophagus and spinal cord; surgical site infection (superficial or deep). Late surgical complications including adjacent disc disease; progressive cervical kyphosis; implant pullout/subsidence; aseptic discitis and medical complications including urinary tract infection; upper respiratory tract infection; deep vein thrombosis/pulmonary embolism; myocardial infarct; stroke; death.

Sample size

In this study, the sample size was calculated according to \(\alpha=0.05, \beta=0.2\), sample ratio 1:1, and the JOA score of 150 patients with DCM from 2017 to 2019 in our hospital at 1 year after surgery was taken into account, \(\mu_A=15.5, \mu_B=15.1, \sigma=1.1\). A total of 95 samples were calculated for each group. When the shedding rate was set at 20%, the final sample size was 238 cases. According to the actual situation of each centre, 260 subjects will be included in this study. We expect to complete subject recruitment within 2 years. Subjects will be recruited on 1 January 2021.

Statistical analysis

Both sets of baseline data will include demographic information, general conditions prior to intervention and baseline indicators that may influence prognosis. The mean, SD and CI of the measurement data will be given, and the minimum, maximum, P25, median and P75 will be provided when necessary. Measurement data shall be tested by \(t\)-test or a non-parametric \(t\)-test (when variance is uneven); the Pearson\textsuperscript{2} test will be used for counting data; Wilcoxon two-sample rank sum test will be used for grade data. The Pearson\textsuperscript{2} test will be used to compare the incidence of adverse events between the two groups. A p value less than 0.05 will be considered statistically significant. The analysis will be performed using appropriate statistical software, such as SPSS.

ETHICS AND DISSEMINATION

This article describes a protocol for a prospective, non-inferiority RCT to examine the efficacy of CPC and PCER in the patients of ACFD. Informed consent will be obtained prior to randomisation from all eligible participants (online supplemental appendix 1). Results of the research will be published in an international peer-reviewed scientific journal and disseminated through presentation at scientific conferences.

Contributors All authors are the principal investigators and have coordinated all the phases of trial design, statistical analysis plan and drafting of the protocol. G-QZ, Y-JL and CC completed the conception and design of the project. BL and ZL carried out the acquisition of data or analysis and interpretation of data. BL, RQL
and ZL wrote the manuscript. All authors contributed to refinement of the study protocol and approval of the final manuscript.

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**ORCID iDs**
Ren Qin Lin http://orcid.org/0000-0003-4479-1556
Chun Mei Chen http://orcid.org/0000-0002-4483-7465

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