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New scoring system for neck tumors: Improving surgical planning and patient outcomes

Submission date	**Recruitment status**	[_] Prospectively registered
20/08/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
22/08/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/08/2024	Cancer	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is focused on improving the safety and effectiveness of surgeries for patients with a specific type of tumor in the neck and spine, known as dumbbell tumors. These tumors can affect both the spinal canal and areas outside of it, making surgery complicated. The aim of the study is to develop and test a new scoring and classification system that can help doctors plan these surgeries better. By using this system, doctors hope to reduce the risks of complications after surgery and improve recovery for patients.

Who can participate?
The study involved 144 patients who had dumbbell tumors in the cervical (neck) area of the spine and were scheduled for surgery. Participants were those who required surgical treatment and were willing to undergo the procedures being studied.

What does the study involve?
Participants in the study underwent surgery to remove their tumors. Before surgery, doctors used advanced imaging techniques, like MRI and special CT scans, to gather detailed information about the tumors. This information was then used to score and classify the tumors based on their size, location, and how close they were to important structures like the spinal cord and arteries. This classification helped guide the surgical approach.

What are the possible benefits and risks of participating?
No additional risks from routine treatment

Where is the study run from?
China-Japan Union Hospital of Jilin University (China)

When is the study starting and how long is it expected to run for?
January 2016 to December 2023

Who is funding the study?
China-Japan Union Hospital of Jilin University (China)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Application of a novel scoring and classification method in surgery for primary cervical spine dumbbell tumors

Acronym
CSDT-SCS

Study objectives
1. A new scoring and classification system can be developed for cervical dumbbell tumors based on their anatomical characteristics and growth patterns
2. This new scoring and classification system will provide more accurate guidance for surgical planning compared to existing systems
3. The application of this new system will lead to improved surgical outcomes and reduced complications in patients with cervical dumbbell tumors
4. The new system will demonstrate high inter-observer reliability and reproducibility among different surgeons

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 24/06/2024, Ethics Committee of the Second Hospital of Jilin University (Jilin University Second Hospital Bethune, Changchun, 130000, China; +86-0431-81136334 ; 1312600916@qq.com), ref: No. 264 of 2024

Study design
Single-center retrospective observational study

Primary study design
Observational

Study type(s)
Diagnostic, Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied
Cervical spine dumbbell tumors

Interventions
This study does not involve any direct interventions on patients. The research process involves the following steps:

Retrospective review of medical records and imaging data of adult patients who underwent surgical treatment for cervical dumbbell tumors.

Development of a new scoring and classification system based on the anatomical characteristics and growth patterns of cervical dumbbell tumors observed in the collected data.

Application of the new scoring and classification system to the existing patient data to evaluate its effectiveness in surgical planning and outcome prediction.

Analysis of surgical outcomes and complications in relation to the new scoring and classification system.

Assessment of inter-observer reliability of the new system through independent evaluation by multiple surgeons.

Intervention Type
Other

Primary outcome(s)
The effectiveness of the new scoring and classification system for cervical dumbbell tumors is assessed by its ability to predict surgical outcomes and complications. This is measured by:
1. The correlation between the preoperative tumor score/classification and the extent of surgical resection (complete vs. partial) as determined by postoperative imaging at 3 months post-surgery.
2. The association between the preoperative tumor score/classification and the occurrence of surgical complications, evaluated during the immediate postoperative period and at follow-up visits at 1, 3, and 6 months post-surgery.
3. Inter-observer reliability of the new system, measured using the intraclass correlation coefficient (ICC) for continuous scores and Cohen's kappa for categorical classifications, assessed by independent evaluations from at least three neurosurgeons.

Key secondary outcome(s))
1. Neurological function improvement measured using the Japanese Orthopaedic Association (JOA) score at baseline (preoperative) and at 3, 6, and 12 months postoperatively.
2. Pain reduction assessed using the Visual Analog Scale (VAS) at baseline (preoperative) and at 1, 3, 6, and 12 months postoperatively.
3. Quality of life changes evaluated using the Short Form-36 (SF-36) questionnaire at baseline (preoperative) and at 6 and 12 months postoperatively.
4. Tumor recurrence rate determined by follow-up MRI scans at 12 months and annually thereafter for 5 years post-surgery.
5. Long-term surgical complication rates (e.g., cerebrospinal fluid leakage, wound infection) assessed during follow-up visits at 1, 3, 6, and 12 months postoperatively, and annually thereafter for 5 years.
6. The correlation between tumor location (as classified by the new system) and the surgical approach chosen, analyzed retrospectively from surgical records.
7. Patient satisfaction with surgical outcomes measured using a custom 5-point Likert scale questionnaire at 6 and 12 months postoperatively.

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Adult patients aged 18 years or older at the time of surgery
2. Diagnosed with cervical dumbbell tumor confirmed by MRI
3. Underwent surgical treatment for the tumor between January 1, 2010 and December 31, 2020
4. Complete medical records available, including:
4.1. Preoperative imaging (MRI and/or CT scans)
4.2. Detailed surgical records
4.3. Postoperative follow-up data for at least 12 months
5. Tumor histologically confirmed as one of the following types:
5.1. Schwannoma
5.2. Neurofibroma
5.3. Other nerve sheath tumors
6. Ability to provide informed consent for the use of medical data in research (or appropriate proxy consent if patient is incapacitated)
7. Patients with both primary and recurrent cervical dumbbell tumors are eligible

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
23 years

Upper age limit
65 years

Sex
All

Total final enrolment
144

Key exclusion criteria
1. Patients younger than 18 years at the time of surgery
2. Incomplete medical records or imaging data, including:
2.1. Missing preoperative MRI or CT scans
2.2. Incomplete surgical records
2.3. Less than 12 months of postoperative follow-up data
3. Patients who underwent non-surgical treatment for their cervical dumbbell tumor
4. Patients with a history of previous cervical spine surgery unrelated to the dumbbell tumor
5. Patients with concurrent spinal cord tumors not classified as dumbbell tumors
6. Patients with severe comorbidities that significantly impact neurological function or surgical outcomes, such as:
6.1. Advanced neurodegenerative diseases (e.g., advanced Parkinson's disease, multiple sclerosis)
6.2. Severe spinal deformities
6.3. Active systemic malignancies
7. Pregnant women at the time of surgery
8. Patients unable to provide informed consent for the use of their medical data in research (and no appropriate proxy available)
9. Tumors histologically confirmed to be types other than schwannomas, neurofibromas, or nerve sheath tumors
10. Patients who received preoperative radiotherapy or chemotherapy for the cervical dumbbell tumor

Date of first enrolment
01/01/2016

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
China

Study participating centre
China-Japan Union Hospital of Jilin University
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Study participating centre
The Second Hospital of Jilin University
No. 218 Ziqiang Street, Changchun City, Jilin Province
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Sponsor information

Organisation
China-Japan Union Hospital of Jilin University

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
China-Japan Union Hospital of Jilin University

Results and Publications

Individual participant data (IPD) sharing plan
What data will be shared: De-identified individual participant data that underlie the results reported in the main publication, including demographic information, clinical characteristics, imaging findings, surgical details, and outcome measures.
What additional, related documents will be available: Study protocol, statistical analysis plan, informed consent form, and clinical study report.
When data will be available: Data will be available beginning 9 months and ending 36 months following article publication.
With whom data will be shared: Researchers who provide a methodologically sound proposal and whose proposed use of the data has been approved by an independent review committee.
For what types of analyses: To achieve aims in the approved proposal.
By what mechanism data will be made available: Proposals should be directed to gyc@jlu.edu.cn. To gain access, data requestors will need to sign a data access agreement and obtain necessary ethical approvals for their proposed use of the data.
Data sharing restrictions: Data will be de-identified in compliance with local privacy laws. Users must agree not to attempt to re-identify participants and to use the data only for the approved purpose.
Data security: Data will be shared via a secure, password-protected data sharing platform.

This plan is subject to change to protect participant privacy and comply with evolving data protection regulations.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			22/08/2024	No	Yes
Participant information sheet	in Chinese		22/08/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	in Chinese		22/08/2024	No	No
Statistical Analysis Plan	in Chinese		22/08/2024	No	No