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Role of a route map in learning lumbar spinal ultrasonography: a study protocol for a randomised, controlled teaching study

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ABSTRACT

Introduction Lumbar spinal ultrasonography is an important tool used by pain physicians and anaesthesiologists to perform pain-related scanning, interventional treatments and anaesthesia in clinical practice. However, ultrasound images of the lumbar spine are complex and numerous. Moreover, long learning curves are necessary for novice physicians to memorise, master and apply this modality in their clinical practice. This study will use our team's recent teaching research achievement, the 'spinal ultrasound route map', as a teaching tool to comprehensively compare learning effectiveness and satisfaction between novices learning with or without this route map. The appropriate time point at which to introduce the route map in the teaching process will also be evaluated.

Methods and analysis This randomised, controlled teaching study with a target sample size of 40 clinicians will be carried out at Peking Union Medical College Hospital. Eligible participants will be randomly allocated to group 1 or group 2. Participants in group 1 will receive traditional lumbar ultrasonography training, followed by teaching with the route map. Participants in group 2 will receive training directly with the route map. There will be questionnaires, timed tests and gradings from teachers throughout the training process. The data will be collected via the Q1, Q2 and Q3 questionnaires and the timed test. The primary outcome is the composite learning score, which will be measured when group 1 participants fill out questionnaire Q2 after traditional training and group 2 participants fill out questionnaire Q3 after training with the route map. The secondary outcomes will include the composite learning score at different time points, the results of the timed test, grading scale scores from teachers and the participants' satisfaction with the route map.

Ethics and dissemination This study received authorisation from the Institutional Review Board on 11 April 2024. The study findings will be disseminated through presentations at scientific conferences or publications in peer-reviewed journals.

Trial registration number ChiCTR2400084604.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ In this study, the effectiveness of learning is evaluated through various means, including self-assessment, teacher evaluation and timed tests.
⇒ It is a randomised, controlled, registered teaching trial, with strong universal applicability and high-quality evidence.
⇒ In addition to the efficacy of the route map, this study will also explore when to introduce the route map to learners, whether it is brought in after a traditional course or immediately and directly taught.
⇒ As an open-label trial, all participants and some of the investigators will be aware of the group assignments, and thus, their expectations may introduce bias.

INTRODUCTION

Ultrasound-guided spinal pain interventional therapy and spinal anaesthesia have many advantages. It is visual, cost-effective and free of ionising radiation; moreover, it provides real-time guidance, high spatial resolution and excellent soft tissue contrast.[1] However, spinal ultrasonography can be difficult to learn since it involves abundant anatomical details and numerous scanning planes. Compared with cervical, thoracic and sacrococcygeal spine ultrasound, lumbar spinal ultrasound is applied in broader scenarios, such as lumbar spinal intrathecal anaesthesia and pain treatment for lumbar region spondyloarthropathy.[2 3]

Currently, ultrasonography is increasingly being integrated into medical curricula to prepare students for clinical practice. Ultrasound teaching is well received by trainees, with reported improvements in confidence in the use of ultrasound, motivation to learn anatomy and retention of knowledge.[4] Spinal ultrasonography reveals anatomic structures such as the transverse process, spinous process, epidural space, articular process, spinal canal and lamina, which enables learners to understand regional and ultrasonic anatomy. Training in method exploration involves teaching trials aimed to improve

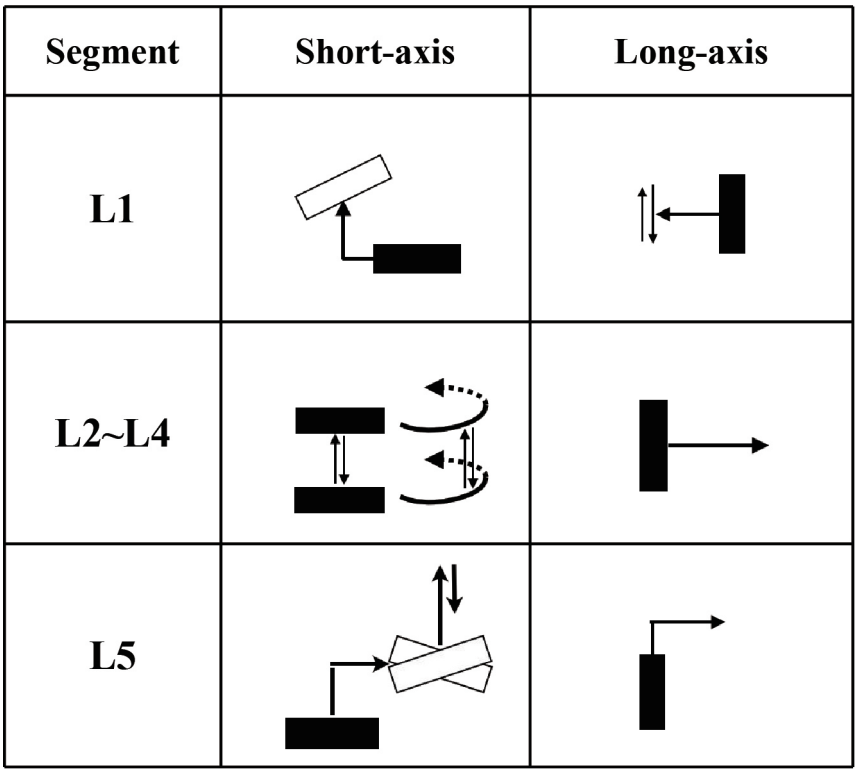

Figure 1 The express edition of the lumbar ultrasonography route map.

the efficacy of spinal ultrasound,[5] and certain visual teaching methods are proposed for ultrasound-guided lumbar region interventional therapy.[6 7] In regional anaesthesia,[8] cardiac ultrasound,[9] critical care medicine,[10] and especially point-of-care,[11 12] ultrasound scanning route protocols are widely proposed and used. However, scanning routes have been rarely reported in spinal ultrasonography. Recently, our team proposed the use of a route map as a teaching tool for beginners learning cervical ultrasonography and verified the clinical feasibility of this tool with electronic simulation anatomy software.[13] The route map is delineated with rectangles, lines, and arrows to articulate the scanning route of cervical ultrasonography. We have generalised the route map in the lumbar region (figure 1) and intend to verify the usefulness of this tool for learners to progress beyond their learning curve when studying lumbar spinal ultrasonography. The proper time to introduce the route map to learners will also be explored.

Overview, interpretation of the route map and the scanning protocol

In the route map, rectangles represent the positions of the transducer. A convex array probe is usually employed for ultrasound scanning in the lumbar region (L1–L5). The black rectangles mark the initial points, while the white rectangles mark the via points or terminus of the transducer. Arrows indicate the route direction. The solid lines show the transducer route paths on the initial side of the body, and the dashed lines indicate the paths to other aspects, which are either anterior, posterior, anterolateral, posterolateral or lateral. Ultrasonography is performed along both the short and the long axes of the lumbar spine.

The ultrasonic imaging and scanning methods used for each vertebra are similar at L2–L4. The structure of L1 and L5 resembles that of L2–L4; however, the head of L1 connects with that of T12 and is close to the coeliac plexus. L5 is connected to the sacrum and ilium. Thus, L1 and L5 are described separately in the route map.

Short-axis ultrasonography of L1

Only two scanning planes are used for L1 short-axis ultrasonography. Starting from position 1, the plane of the facet joints and the interlaminar space can be seen. Next, the device is moved laterally to the oblique axis to avoid the 12th rib, while the transducer is tilted inward to the vertebra. The articular processes, vertebral body, aorta, adrenal gland or kidney can be observed at this position. Anterior to the aorta lies the coeliac plexus, which usually appears at the level of T12–L1; in a few cases, it appears at the level of T11–T12 (figure 2A).

Long-axis ultrasonography of L1

There are two scanning planes used for long-axis ultrasonography of L1. Start from position 1 and slowly slide laterally to position 2. The transverse process of T12 is connected to the 12th rib, but that of L1 is not; this helps us to identify the L1 and T12 vertebrae. As a result, other lumbar and thoracic vertebrae can be further identified accordingly (figure 2B).

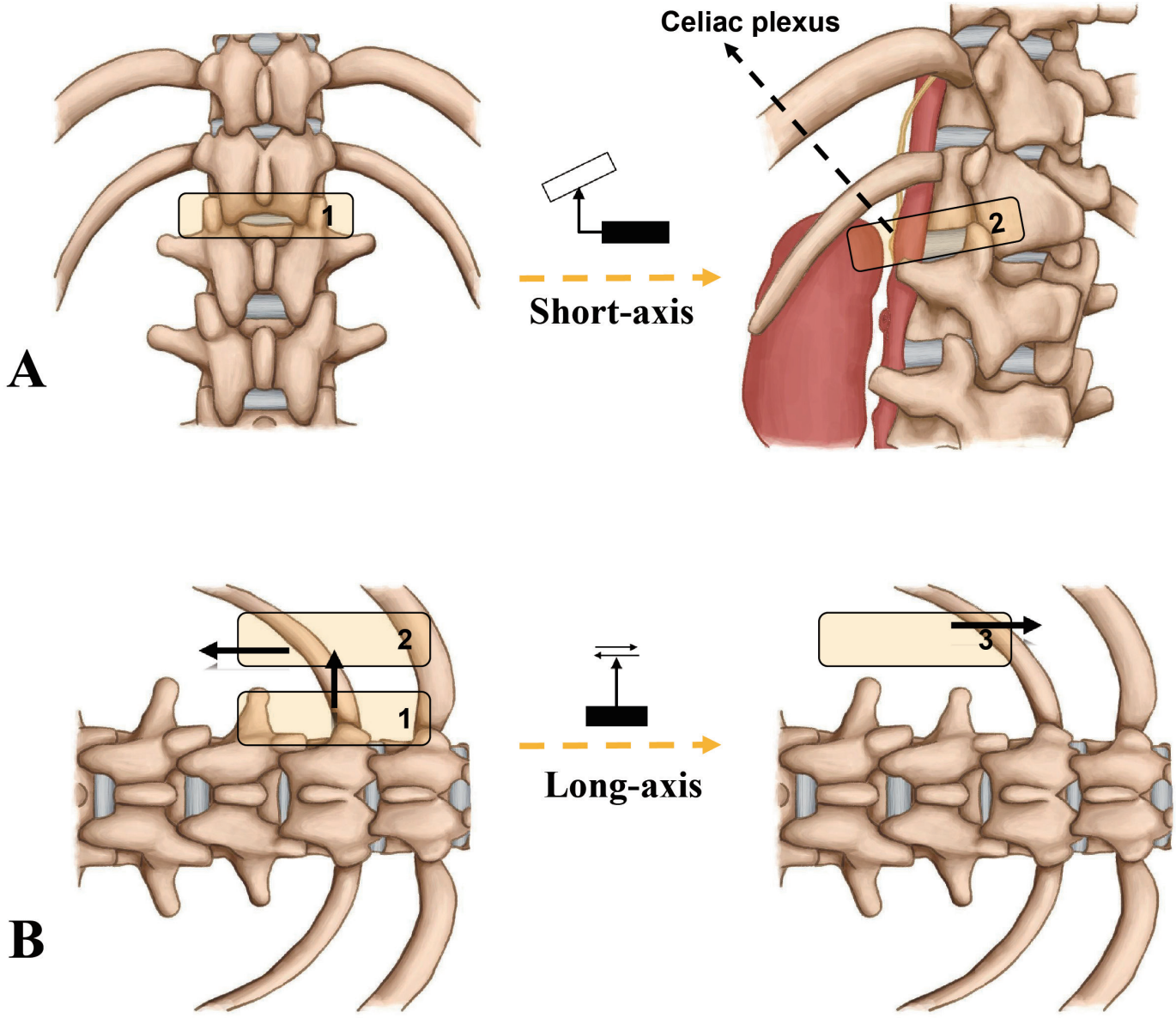

Figure 2 The programmed travel routes for the ultrasound scan route map of the upper lumbar region, including both the anatomical diagram and the simple ultrasonography route map. (A) short-axis; (B) long axis.

Short-axis ultrasonography of L2–L4

First, the bilateral facet joints were scanned at position 1. The anterior and posterior complexes can be seen through the interlaminar space at this point in most cases. This section can be used for lumbar puncture.[14] In addition, injection of the facet joints can also be performed here.[2] Next, the patient is relocated to position 2 to scan the superior articular process and the transverse process. Pain physicians and anaesthesiologists can carry out medial branch injection and erector spinae plane block at this point. The lumbar plexus block or quadratus psoas block is scanned at position 3. The psoas major, quadratus lumborum and erector spinae muscles compose the classic shamrock pattern here.[15] Then, the device moves downward to position 4 from position 1. The spinous process and vertebral laminae will be reached, and the nerve root can be confirmed with the help of electrical stimulation. The nerve root can be located more precisely at position 5, where the spinous process, laminae and vertebral body are shown in the same plane. In this ultrasound plane, the nerve root lies in the corner between the lamina and vertebral body. Lumbar plexus block and lumbar sympathetic nerve interventions can also be performed here.[7] Finally, when aligning downward from position 5 to 6 or moving from position 4 to 6, the ultrasound beam is directed towards the lumbar disc; consequently, this plane is usually utilised in lumbar disc interventions (figure 3A).

Long-axis ultrasonography of L2–L4

The transducer is placed along the sagittal plane along the spinous process connection of the lumbar region at position 1. The supraspinous ligaments and interspinous ligaments, as well as the posterior and

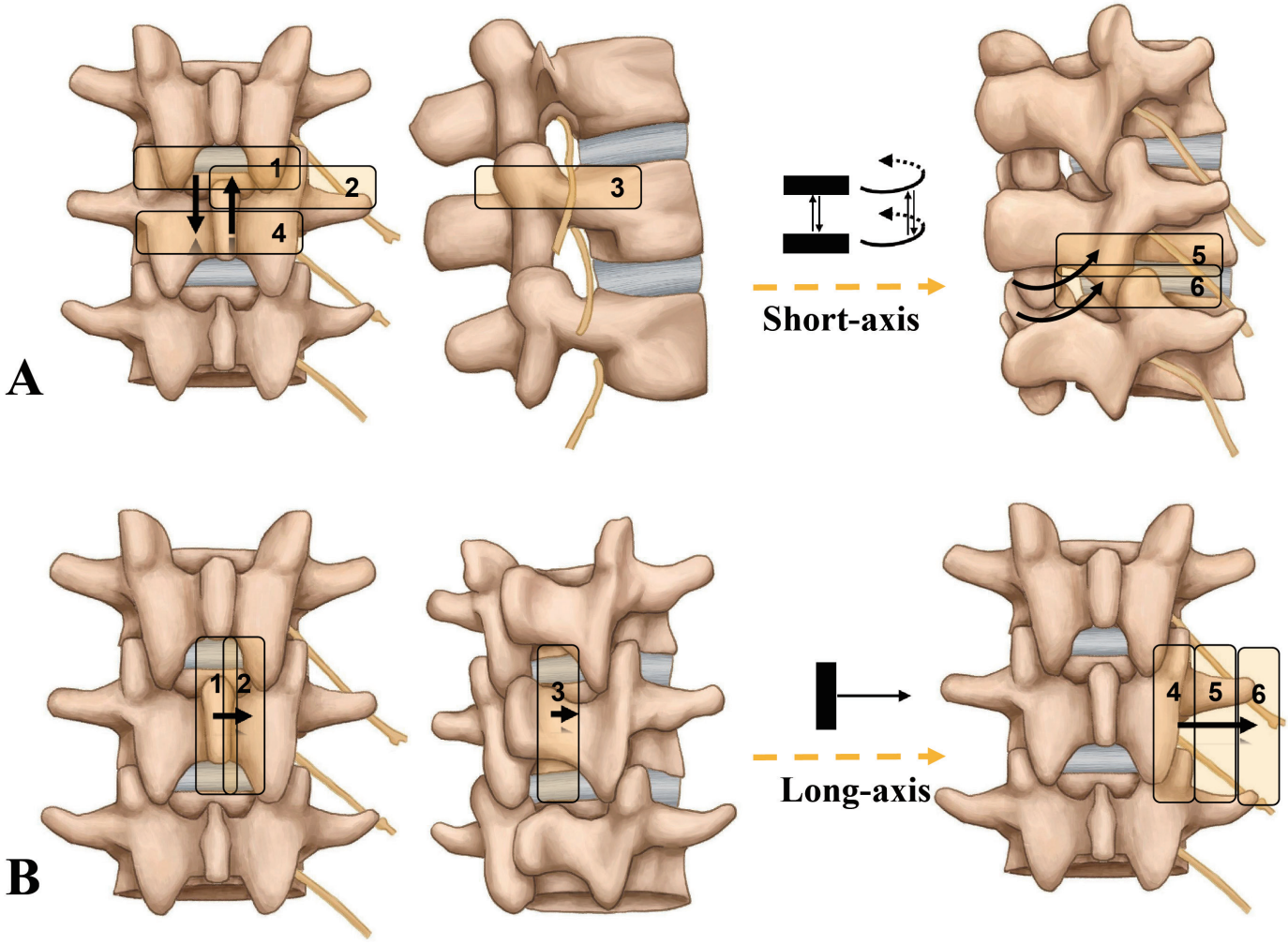

Figure 3 The programmed travel routes for the ultrasound scan route map of the middle lumbar region, including both the anatomical diagram and the simple ultrasonography route map. (A) short-axis; (B) long axis.

anterior complex, can be visualised in most cases.[16] Sliding the transducer laterally to position 2, the hyperechoic, horse-head-like laminae can be located here. By tilting the transducer to allow the ultrasound beam to be more perpendicular to the spinal canal at position 3, the dura, ligamentum flavum and epidural space between them can be recognised.[17] This plane can be used to facilitate intrathecal or epidural injection.[18] The transducer is relocated more laterally to position 4 to view the facet joints, which resemble camel humps.[19] Then, more laterally to position 5, 'the trident sign', which is the acoustic shadow of the transverse processes, is observed. Erector spinae plane block and psoas major space block can be carried out at this point.[20] Continuing to move laterally and to pivot the transducer towards the midline to position 6 until reaching the erector spinae muscle, the quadratus lumborum muscle and psoas major muscle can be clearly seen from the shallow to the deep aspect. The superior gluteal cutaneous nerve courses between the erector spinae and quadratus lumborum muscle (figure 3B).

Short-axis ultrasonography of L5

First, the transducer is placed at position 1 to observe the 'moustache sign', which is composed of the sacrum, the posterior sacroiliac ligaments and the cast of two oblique iliac bones. Then, the incision is advanced cranially to position 2, and the L5/S1 interlaminar space, facet joints and intervertebral disc are clearly visible. The L5 nerve root and dorsal ramus can be located at position 3, between the S1 vertebra superior articular process and the sacral ala.[21] After adjustment to position 4, the L5/S1 disc can be reached below the S1 superior articular process. Then, moving cranially to position 5 will enable images of the L5 superior articular process, transverse process and iliolumbar ligament to be obtained. The L4 medial branch can be approached between the L5 superior articular process and the L5 transverse process.[22] Periligamentous injection can also be carried out here since iliolumbar ligamentitis is a common cause of low back pain. Sliding caudally until the disappearance of the L5 transverse process, the lumbosacral tunnel can be seen between the L5

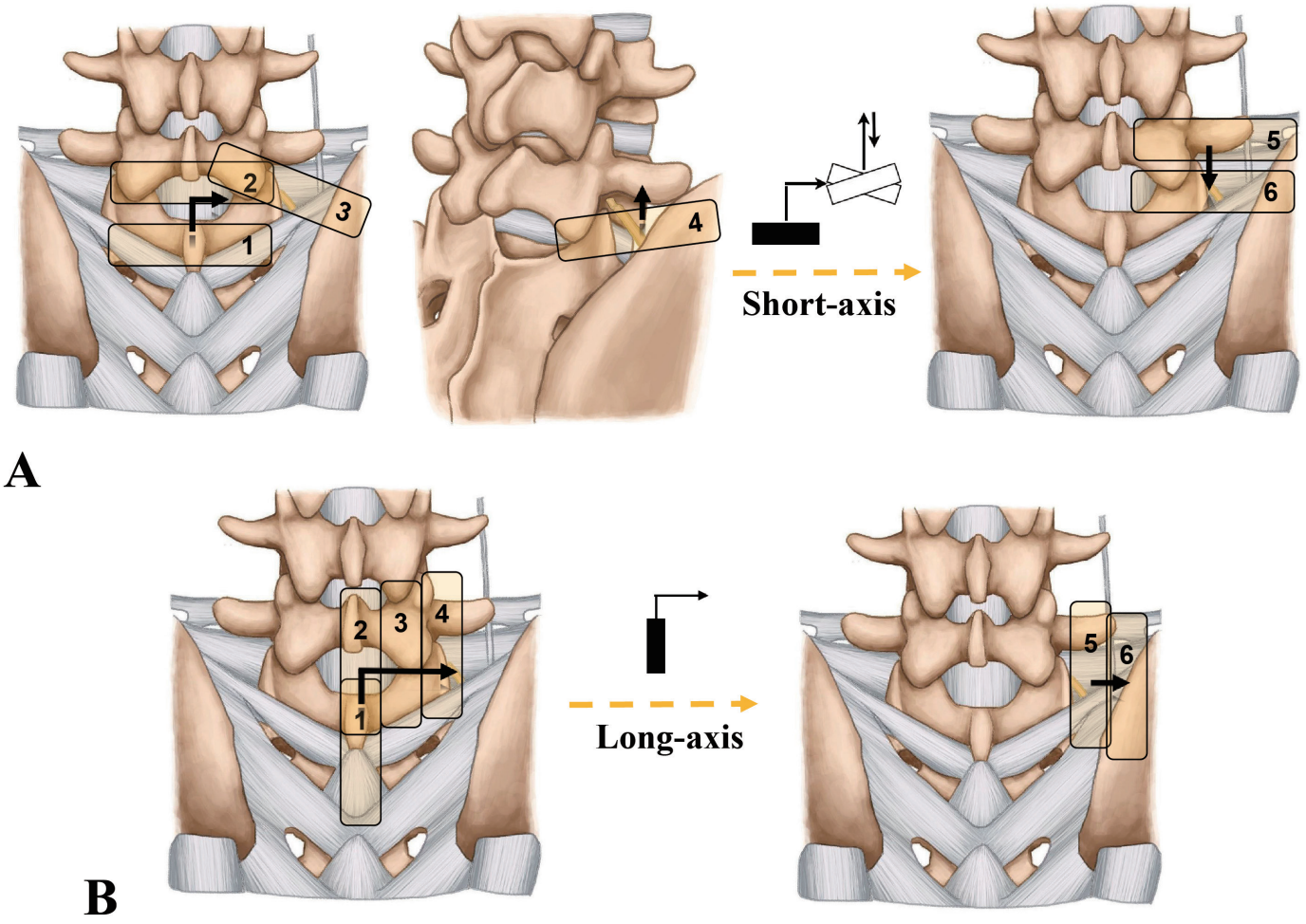

Figure 4 The programmed travel routes for the ultrasound scan route map of the lower lumbar region, including both the anatomical diagram and the simple ultrasonography route map. (A) short-axis; (B) long axis.

lamina and ilium at position 6. The L5 nerve root runs through the lumbosacral tunnel, which is wrapped by the intertransverse ligament and iliolumbar ligament from shallow to deep layers (figure 4A).

Long-axis ultrasonography of L5

The median sacral crest is started at position 1, and the canal is then moved cranially to position 2 to reach the L5/S1 interlaminar space, which is the first bony discontinuity along the sagittal plane. Movement laterally to position 3 reveals the horse head-like laminae, and movement to position 4 allows the L5/S1 facet joint and L5/S1 nerve root to be reached.[23] The L5 transverse process and sacrum ala can be viewed by continuing to move laterally to position 5 until the facet joints disappear. As mentioned above, the lumbosacral tunnel can be located here, through which the L5 nerve root travels. The L5 medial branch can also be viewed on the surface of the sacrum ala in this plane, after which the transducer can move laterally to position 6 near the lateral end of the L5 transverse process. In addition to lumbosacral tunnel injection, this technique is used in the out-of-plane approach for lumbosacral plexus blocks, in which the needle tip must pass through the lumbosacral ligament to reach the retropsoas space (figure 4B).[20]

OBJECTIVE

The primary objective of this randomised controlled teaching study is to compare the efficiency of learning lumbar ultrasonography between trainees using a route map and trainees learning with traditional methods. The secondary objective of this study is to compare the learning efficiency between trainees learning lumbar ultrasonography initially with traditional methods followed by the introduction of the route map and trainees directly learning via the route map. Learner satisfaction with the route map will also be evaluated.

METHODS AND ANALYSIS

Overall design

This trial is a randomised, controlled teaching study and will be carried out in Peking Union

Medical College Hospital (PUMCH). Institutional research ethics board approval was obtained form PUMCH Institutional Review Board (IRB) (no. I-24PJ0791, 11

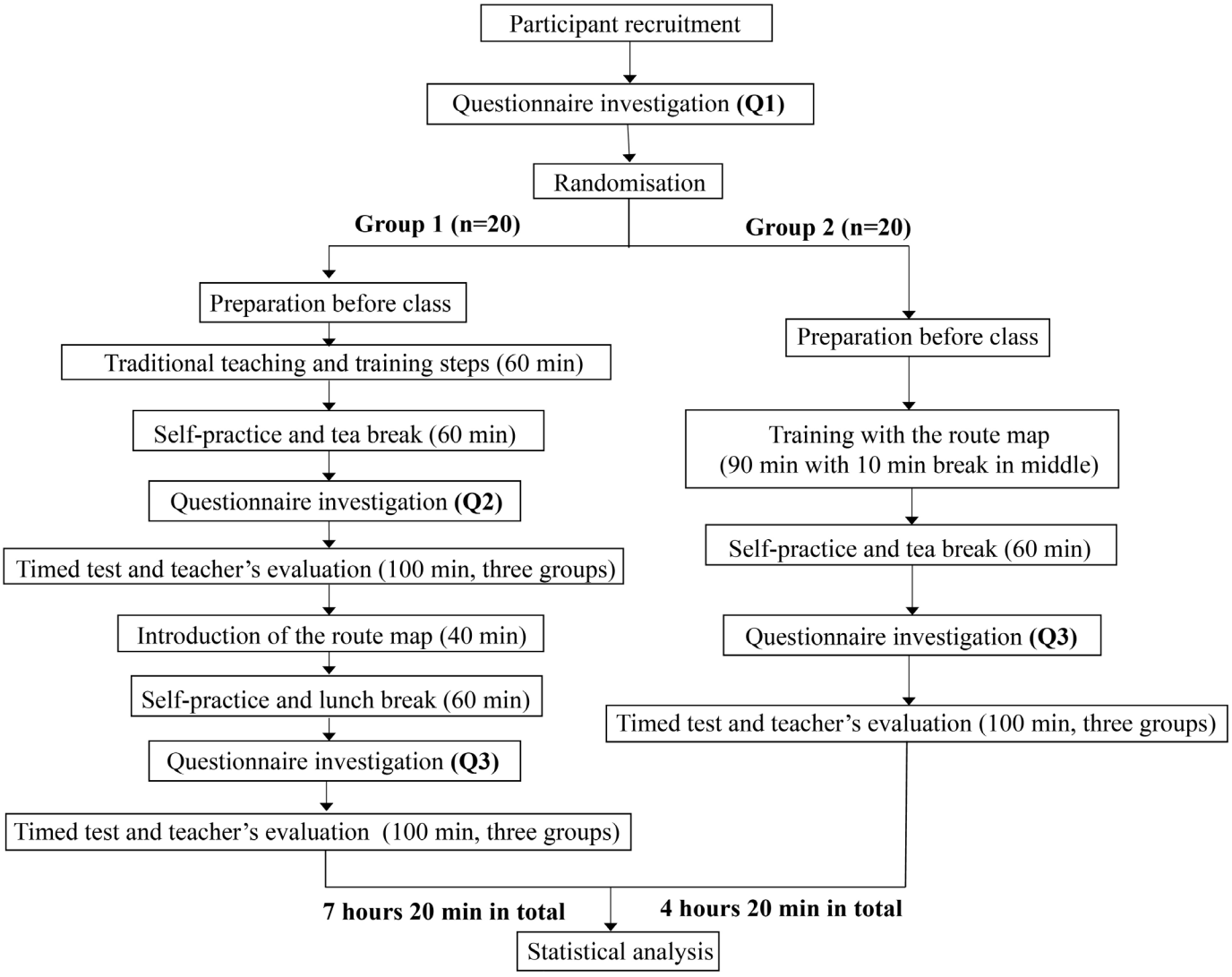

Figure 5 Study process diagram.

April 2024). An overall flow diagram is provided in figure 5. This protocol was designed in accordance with the Standard Protocol Items: Recommendation for Interventional Trial guidelines,[24] the checklist can be found in online supplemental appendix 1.

Recruitment

Recruitment for this study will begin on 1 June 2024. Each participant will sign informed consent form, prior to randomisation. Postgraduate physician trainees or resident anaesthesiologists at PUMCH who are willing to participate in the study during this period will be enrolled. Additional inclusion criteria are as follows:

- Have more than 1 month of ultrasound experience, that is, understand the basic knowledge and principles of ultrasound, know how to operate an ultrasound machine, is familiar with identifying anatomical structures under ultrasound, and possess basic ultrasound scanning capabilities.
- Have basic knowledge of lumbar musculoskeletal anatomy.
- Have not undergone systematic training in lumbar ultrasound.
- Have completed less than five lumbar spinal ultrasound scans or punctures in the past.

Participants who are experts in lumbar ultrasonography or who are not willing to start/continue their participation will be excluded or withdrawn from the study.

Randomisation, sequence concealment and blinding

After the baseline questionnaire investigation (Q1) has been completed, all eligible participants will be randomly allocated to either group 1 or group 2 at a ratio of 1:1 using R software (R Foundation for Statistical Computing). The random allocation sequence will be computer-generated by an independent researcher who has no contact with any participant and will not be involved in the following research. This study is an open-label teaching study because of the nature of the teaching process. However, the researchers who are responsible for the statistical analysis will be blinded to the allocation.

Teaching process

The traditional training group (group 1)

After recruitment and allocation, participants in group 1 will receive teaching at 8 am on a weekend day. Three days before the training day, participants in group 1 will receive a paper copy and an electronic copy of the lumbar spine ultrasound anatomy and scanning sectional teaching plan (not involving the route map), which can be used for repeated reading and learning. On the training day, Professor Xulei Cui, a member of the research team, will conduct traditional teaching of lumbar spine ultrasound (60 min) to the participants without using the route map. After a 60 min self-practice and tea break, the Q2 questionnaire will be distributed to the participants and collected. Then, the participants will receive a timed test. The time required to find the coeliac plexus at the T12–L1 level, any facet joints in the middle lumbar segment (L2–L5) and the lower lumbar L5 nerve root will be documented. If one target fails to be found within 5 min, this target will be recorded as a failure. The participants will be divided into three groups for the timed test, which will be conducted by teachers Si Chen, Jiao Zhang and Gang Tan, respectively. Moreover, teachers will evaluate each participant's scanning ability using a rating scale. After the timed test and teachers' evaluation, Professor Xulei Cui will introduce and explain the lumbar spine ultrasound route map to the participants (40 min), and then there will be a 60 min self-practice session and lunch break. At the end of the break, questionnaire Q3 will be distributed and collected, after which the above timed test and teacher's evaluation will be repeated.

The route-map training group (group 2)

The participants in group 2 will start training at eight am on another weekend day within a month. Three days before the training day, participants in group 2 will receive a paper copy and an electronic copy of the lumbar spine ultrasound anatomy and scanning sectional teaching plan (including the route map), which can be used for repeated reading and learning. On the training day, Professor Xulei Cui will provide lumbar spine ultrasound training and route map introduction and interpretation (90 min, with a 10 min tea break in the middle) to the participants. After a 60 min self-practice and tea break, questionnaire Q3 will be distributed and collected after the course. Then, the participants will receive a timed test consisting of scanning the coeliac plexus at the level of T12–L1, any facet joints in the middle lumbar segment (L2–L5) and the lower lumbar L5 nerve root with the route map. If one target fails to be found within 5 min, this target will be documented as a failure. The participants will be divided into three groups for the timed test, which will be conducted by teachers Si Chen, Jiao Zhang and Gang Tan, respectively. Moreover, teachers will evaluate each participant's scanning ability using a rating scale.

Content of the questionnaires

The content of these self-assessment questionnaires will focus on the participants' theoretical knowledge, practical skills and willingness to use lumbar ultrasound in the future. The Q1 and Q2 questionnaires have the same content. They are designed with three questions (questions 1–3) for the self-assessed theoretical knowledge score, three questions (questions 4–6) for the self-assessed practical skills score and one question for willingness to use lumbar ultrasound in the future (question 7). Four questions on the participants' satisfaction with the route map (questions 8–11) will be added to Q3 on the basis of Q2. The concrete content of the questionnaires is listed below. Answers to these questions will be 10-point scales ranging from 1 to 10, with 1 defined as the minimum degree and 10 defined as the maximum degree.

Question 1. How would you rate your current comprehensive understanding of various sections of lumbar ultrasound?

Question 2. How would you rate your current proficiency level of various sections of lumbar ultrasound?

Question 3. How easy do you currently think it is to use lumbar ultrasound for scanning or interventional treatment?

Question 4. If you use lumbar ultrasound for scanning or interventional treatment, how confident are you in successfully finding the coeliac plexus at the level of T12–L1?

Question 5. If you use lumbar ultrasound for scanning or interventional treatment, how confident are you in successfully finding any facet joint in the middle lumbar segment (L2–L4)?

Question 6. If you use lumbar ultrasound for scanning or interventional treatment, how confident are you in successfully finding the lower lumbar L5 nerve root?

Question 7. Will you use lumbar ultrasound for scanning or interventional treatment in future clinical work?

Question 8. How do you think using the route map will help you learn lumbar ultrasound?

Question 9. Do you think it is necessary to use the route map as a regular teaching tool in the teaching syllabus/workshop for spinal ultrasound?

Question 10. Would you use the route map as an auxiliary tool in future clinical scanning or interventional treatment of lumbar ultrasound?

Question 11. Would you use the route map as a teaching tool if you are engaged in teaching lumbar ultrasound in the future?

Content of the rating scale graded by teacher

The rating scale (table 1) is modified from the Global Rating Scale (GRS) established by Cheung *et al*.[25] The GRS was originally designed to assess students' ability in ultrasound-guided regional anaesthesia. In this study, teachers will use the modified rating scale to evaluate each participant's ability to use ultrasound during the timed test. The 5-point Likert rating scale comprises six items. The items are respect for tissue, time and motion,

Table 1 Rating scale graded by teacher to evaluate participants' scanning behaviour

Score					
Item	1	2	3	4	5
Respect for tissue	Frequently uses unnecessary force on issue		Carefully handles tissue, but occasionally uses unnecessary force unintentionally		Consistently handles tissue appropriately
Time and motion	Many unnecessary movements		Efficient time/motion but some unnecessary movements		Clear economy of movements. Maximum efficiency
Instrument handling	Repeatedly makes tentative and awkward movements		Competent with instruments but occasionally makes awkward or stiff movements		Fluid movements with instruments and no awkwardness
Flow of procedure	Frequently stops procedure and seems unsure of next move		Demonstrates some forward planning with reasonable progression of procedure		Obviously planned course of procedure, with effortless flow from one move to the next
Knowledge of procedure	Deficient knowledge		Knows all important steps of procedure		Demonstrates familiarity with all aspects of procedure.
Overall performance	Very poor		Competent		Clearly superior

instrument handling, flow of procedure, knowledge of procedure and overall performance. The final result will be calculated as overall performance score + (sum value of other five scale items)/5.

Outcomes

Primary outcomes

The primary outcome of this study is the composite learning score, which will be calculated as (self-assessed theoretical knowledge score+self-assessed practical skills score+willingness to use lumbar ultrasound in the future)/3, that is, (sum value of questions 1–7)/7. The measurement time point for group 1 will be when participants complete questionnaire Q2 after traditional training. The measurement time point for group 2 will occur when participants complete questionnaire Q3 after being introduced to the lumbar route map.

Secondary outcomes

The secondary outcomes are as follows:

- The composite learning score between groups at different time points (when participants complete the entire training programme). The measurement time point will be when the participants complete questionnaire Q3 after the introduction of the lumbar route map. The objective of this study was to compare the learning efficiency between learners learning lumbar ultrasonography with traditional methods initially and then with the route map and between learners learning with the route map directly.
- Comparison of the results of the timed test between groups at the same time point as the primary outcome. The success rate and time required to find the coeliac plexus, facet joints and L5 nerve root will be compared between the groups. The measurement time point for group 1 will be when participants complete questionnaire Q2 after traditional training. The measurement time point for group 2 will be when participants complete questionnaire Q3 after being introduced to the lumbar route map.
- Comparison of the results of the timed test between groups when participants complete the entire training programme, including the participants' success rate and time spent finding the coeliac plexus, facet joints and L5 nerve root. The measurement time point will be when the participants complete questionnaire Q3 after introduction of the lumbar route map. The objective is to compare the learning efficiency between trainees learning lumbar ultrasonography initially with traditional methods followed by introduction of the route map and trainees learning directly with the route map.
- Comparison of the teachers' grading scale score between groups at the same time point as the primary outcome. The measurement time point for group 1

will be when participants complete questionnaire Q2 after traditional training. The measurement time point for group 2 will be when participants complete questionnaire Q3 after being introduced to the lumbar route map.
- Comparison of the teachers' grading scale score between groups when participants complete the entire training programme. The measurement time point will be when the participants complete questionnaire Q3 after introduction of the lumbar route map.
- Participants' satisfaction with the route map, which will be calculated as (sum value of questions 8–11)/4. The measurement time point will be when the participants complete questionnaire Q3 after introduction of the lumbar route map.

Patient and public involvement

Patient/participants and the public will not be involved in the development of the research question or in the design of the study. On completion of the study, dissemination of the general study results or the anonymised participants' data will be made on demand.

Sample size

Based on our past experience with ultrasound teaching, we assumed that the mean value of the primary outcome (the composite learning score) in group 1 would be approximately 6, with a SD of 1.5 and that a progression in group 2 of 1.5 SD is significant and normally accepted in studies carried out in the field of education.[26] We used a statistical power of 80% and a two-sided α of 0.05. The target sample size for each group is at least 16 participants. Accounting for the dropout rate, the teaching faculty's ability and the recruitment capacity in our centre, a sample size of 40 (20 for each group) was ultimately determined. The sample size was calculated using PASS V.11.0 (NCSS, LLC., Kaysville, Utah, USA).

Data collection, monitoring and confidentiality

Each participant's subjective learning outcome and learning experience will be collected using questionnaires Q1, Q2 and Q3. The result of the timed test and the teacher's evaluation will be collected using case report forms (CRFs). We will also document their anonymous personal information (including age, sex, education background and years of work) using questionnaire Q1. Each participant's anonymous information, questionnaires Q1, Q2 and Q3, results of the timed test and teacher's evaluation will be properly matched and bound. The collected data will be recorded on paper questionnaires and CRFs, then entered into electronic case report forms (eCRFs) and uploaded to a central server. The questionnaires, CRFs and eCRFs will be kept for at least 3 years after publication in case of any inquiry. A qualified trial expert will be invited in the middle and at the end of the study to ensure that the protocols are being followed. No interim analysis will be performed during the study. Personal information about the enrolled participants will be safely and confidentially kept. The eCRFs and all the data collected will be stored anonymously in the password-protected central server and restricted to relevant members of the research team. Paper copies of the questionnaires and CRFs will be stored in a locked cabinet in the relevant research office.

Statistical analyses

Continuous variables will first be checked for normality via visual inspection of the histogram. Normally distributed continuous variables will be expressed as the mean±SD, and non-normally distributed continuous variables will be expressed as the median and IQR. Categorical variables will be summarised as frequencies and percentages.

The primary outcome, the composite learning score between groups, which is generally normally distributed from experience, will be analysed using Student's t test, and the mean difference with the corresponding one-sided 95% CI will be calculated. Group differences in the secondary outcomes, including the composite learning score, time consumed in the time test, score ascertained in the teacher's evaluation and participants' satisfaction, will be compared with Student's t test. Data with a skewed distribution will be analysed using the Mann–Whitney U test. As categorical variables, the success rate of the timed test will be compared using the χ^2 test. The main analysis will be performed after the study has been completed. Data analysis will be performed according to the intention-to-treat principle. The results of this study will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement.[27] Statistical analyses will be conducted using SPSS V.19.0 (V. 22; SPSS, Chicago, IL, USA). A two-sided $p<0.05$ was considered significant.

Ethics and dissemination

Ethics approval and consent to participate

This research project was approved by the IRB (I-24PJ0791) at PUMCH on 11 April 2024. Important protocol amendments will be communicated to relevant parties (eg, investigators, IRB, trial participants, trial registries and journals) by Dr Xulei Cui, a trial principal investigator, as soon as changes are made. Written informed consent (for details, see online supplemental appendix 2) will be obtained from all participants.

Dissemination plan

The results of this study may be presented in national and international meetings and will be submitted for publication to relevant teaching, pain medicine, analgesia or anaesthesia peer-reviewed journals. Authorship eligibility will be ascertained in accordance with guideline 3 of the Good Publication Practice guidelines.

Steering Committee, Data and Safety Monitoring Committee (DSMC)

The Steering Committee carries the ultimate responsibility for the trial and has access to the final data set. The specific tasks of the Steering Committee are as

follows: final approval of the study protocol, approval of the amendments to the study protocol and approval of the manuscript and publications. The members of the Steering Committee in this study include Xulei Cui, a pain physician, and Yuelun Zhang, a statistician.

The DSMC is established to assess the progress of the study, the safety of the data and the critical end points independently from the sponsor and competing interests. The DSMC is chaired by Gang Tan, Si Chen and Jiao Zhang, who are pain physicians and anaesthesiologists.

Trial status and time scale

The study was funded in 2022, and participants will begin to be recruited on 1 June 2024. The recruitment of research participants will last for 1 month.

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Contributors SC obtained ethical approval and drafted the manuscript. XLC is the corresponding author, and she also obtained funding. XLC and JZ conceived the study and participated in its design. YLZ contributed to the statistical analysis. GT critically edited the manuscript. All the authors have read and approved the final manuscript. XLC is the guarantor.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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