# The Effectiveness of Simulation-based Ultrasound-guided Regional Anesthesia Training Programs for Anesthesia Residents: a Prospective Randomized Controlled Trial

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**Research article**

**Keywords:** Simulation-based training, Nerve block, Ultrasound-guided regional anesthesia, Medical education, Assessment

**Posted Date:** January 19th, 2021

**DOI:** https://doi.org/10.21203/rs.3.rs-147928/v1



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# Abstract

## Background

Optimizing educational programs for obtaining and maintaining competency in ultrasound-guided regional anesthesia (UGRA) is needed for anesthesia residents. This study aimed to assess the effectiveness of simulation-based training programs on the UGRA skills of senior anesthesia residents.

## Methods

This prospective assessor-blind randomized controlled trial was conducted in a tertiary hospital in November 2019. Twenty anesthesia residents who had been in a clinical rotation in anesthesiology for 3-5 years were randomly allocated to either the workshop group (WG) or the control group (CG) for pretechnical procedure training on UGRA. Following didactic lectures for both groups, simulation-based workshops were performed only for the WG. All participating trainees were assessed by written examination, ultrasound scanning and anatomy recognition in live human models and ultrasound-guided target injections in porcine meat models. The written examination score, sonographic proficiency scores, time taken to perform the injections and errors were recorded and analyzed.

## Results

The simulation-based training program significantly reduced the time taken for target injections performed by trainees in the WG (183.9±44.8 seconds) compared with those in the CG (239.6±64.2 seconds): mean difference -55.8 (-107.7, -3.7), P=0.037. The error score was also significantly lower in the WG than in the CG. The sonographic proficiency scores of the thoracic paravertebral structures, brachial plexus and femoral nerve scanning were significantly higher for trainees in the WG than for those in the CG, as were the total scores for the four stations on live human models.

## Conclusions

For senior anesthesia residents, the simulation-based training program can improve UGRA skills and might enhance clinical competence.

## Trial Registration

Chinese clinical trial registry, ChiCTR-IPR-1900027585, Principal investigator: Hong Zhang, Date of registration: November 19, 2019 URL: http://www.chictr.org.cn/


# Background

Regional anesthesia, which provides remarkable benefits for patients, is becoming a fundamental skill for all anesthesiologists [1]. Compared with traditional anatomy-based methods, ultrasound-guided regional anesthesia (UGRA), especially the peripheral nerve block technique, improves effectiveness and safety and plays an important role in daily clinical practices [1].

The use of ultrasound has been explicitly recommended in almost all guidelines on multimodal analgesia for performing peripheral nerve blocks in adults and children [2–6]. However, there remains a lack of evidence on how best to teach residents about the related knowledge and skills necessary to perform procedures such as UGRA or central venous catheterization (CVC) [7, 8]. The American Society of Regional Anesthesia and Pain Medicine (ASRA) and the European Society of Regional Anesthesia and Pain Therapy Joint Committee (ESRA) made further recommendations for education and training in UGRA [9], and several trials have been designed and performed to explore how providers learn the necessary skills and knowledge according to these guidelines [10–13]. Nevertheless, the specific modality or combination of modalities to be utilized remains to be ascertained [8]. High-quality evidence is needed to optimize educational programs for obtaining and maintaining competency in UGRA, which ultimately benefits patient care.

There is considerable and mounting evidence that simulation-based medical education approaches are more effective in technical skill acquisition than traditional didactic methods alone [14, 15]. As both technology and patient care become increasingly complex, simulation-based medical education provides a practical alternative that allows trainees to practice without harming patients [16]. It has been reported that simulation-enhanced training significantly improved anatomic structure acquisition and ultrasound skills for medical students and residents [8, 9, 12, 13]. However, these findings have not been broadly incorporated into the academic UGRA training curriculum. Evidence for the assessment of simulation-based training is also limited [12, 13, 17]. The aim of this study was to systematically assess the effectiveness of a simulation-based UGRA training program on improving the skills of ultrasound-guided target injection and sonographic proficiency in senior anesthesia residents.

# Methods

### Study design

This randomized assessor-blind controlled trial with two parallel arms was conducted at Peking University First Hospital. Prior to enrollment, the study protocol was approved by the local Ethics Committee (2019-222) and was registered prospectively at chictr.org.cn (ChiCTR-IPR-1900027585, Principal investigator: Hong Zhang, Date of registration: November 19, 2019). Written informed consent was obtained from all participating trainees.

### Participants

Anesthesia residents in a clinical rotation in anesthesiology for more than 3 years were screened for eligibility. Residents who had previous systematic experience with ultrasound-guided nerve block or who were unwilling to participate in this study were excluded.

Prior to training, we sent a questionnaire survey to collect baseline data, including sex, age, handedness, educational background, years on rotation in anesthesiology, and previous experience with ultrasound-guided procedures.

### Randomization, training course and assessment

Trainees were randomly assigned within blocks of rotation years into the workshop group (WG) or the control group (CG) according to a computerized random number generator by an independent biostatistician (Xue-Ying Li) in a 1:1 ratio using the SAS 9.3 statistical package (SAS Institute, Cary, NC, USA).

All trainees received didactic lectures on the basics of ultrasound (30 minutes), transverse abdominis plane block (TAP) (30 minutes), thoracic paravertebral block (PVB) (30 minutes), brachial plexus block (BPB) (30 minutes), and femoral nerve block (FNB) (30 minutes). To minimize fatigue, there were 10-minute breaks between the lectures. The acquisition and recognition of sonographic images of the nerves and plane layers were emphasized. Additionally, the trainees in the WG received five fifteen-minute one-to-one interactive simulation-based training sessions on the following topics: TAP, PVB, BPB, FNB and UGRA skills. The sessions were facilitated by five senior anesthesiologists (YTL, XL, HK, DH and FZ) who designed and prepared the sessions collectively. The workshop on UGRA skills used a silicon model for interactive practice of needle visualization for single-injection and continuous UGRA, while the other workshops used human volunteers for ultrasound scanning and sonographic structure recognition. The four human volunteers who remained throughout the training were recruited and consented to participate in each session to ensure the same conditions for each trainee. Real-time feedback with skill adjustments on UGRA was immediately provided during the workshop period.

The knowledge and skills of the trainees in both groups were subsequently assessed by five assessors (HZ, FC, ZZX, ZTM, ZML) who had not been involved in the previous training and who were completely blinded to the groupings. They were in charge of five assessment stations (TAP, PVB, BPB and FNB ultrasound scanning in live human models and UGRA procedure in porcine meat models), and prior to any assessments, consensus training was conducted to instruct these assessors to execute an identical evaluation standard for all trainees. One of the authors (HZ) designed 100 multiple choice questions (MCQ) focusing on the five sections mentioned in the didactic lectures to create a 60-minute written examination.

The porcine meat models were established as follows: Model A, porcine meat containing distinguishing fascial layers whose corresponding ultrasound image was similar to the layers in the TAP and PVB (Figure 1); Model B, porcine meat with embedded bovine tendon whose corresponding ultrasound image was similar to the nerve in BPB and FNB (Figure 2), as described by Xu and colleagues [18]. The trainees were instructed to successfully perform a short axis, in-plane ultrasound-guided target injection using the porcine meat models. Identical 22G facet beveled, nonechogenic nerve block needles (Stimuplex D; B Braun, Germany) were used for both the training and the examination. An ultrasound machine with a high frequency 5-13 MHz linear transducer was used (Logiq-e, GE Inc., USA). The ultrasound images, the hand maneuvers of the trainees and the transducer movements were continuously recorded by a learning management solution system (SimCapture, B-line medical, USA) through data records and a video camera (Figure 4). Two evaluators (FZ and ZML) assessed the trainees using video analysis.

The assessment outcomes consisted of three parts: (1) the MCQ in the written examination, which focused on basic ultrasound theory, sonographic anatomy structure recognition and knowledge of clinical applications for four routine nerve blocks (TAP, PVB, BPB and FNB). Each topic included 20 questions. (2) Drawing the anatomy and ultrasound image acquisition and interpretation on four routine nerve blocks (TAP, PVB, BPB and FNB) in live human models. The drawing score for four nerve blocks ranging from a maximum score of 7 to 17 was calculated by summing the anatomical parameters listed in Appendix 1 section 1. The sonographic proficiency score for the four nerve blocks listed in Appendix 1 section 2 was calculated to evaluate proficiency, with a maximum score ranging from 6 to 18. The nerve recognition score for BPB and FNB listed in Appendix 1 section 3 was calculated to identify the terminal branches of the related nerve trunk or plexus. (3) The time taken for ultrasound-guided target injection, the cumulative score of errors and the worst sonographic image score in porcine meat models.

The time taken to correctly complete the nerve block, defined as the time from picking up the transducer to the successful deposition of injectate on two target sites, including 1 ml of saline in a designed layer Model A and 1 ml of saline at the 12 o'clock and 6 o'clock positions relative to the nerve in a designed nerve Model B. The cumulative score of errors defined as the errors detected during the procedure is listed in Appendix 2. The image quality score was defined as the worst image of the simulated nerve in Model A or Model B during the procedure, scored numerically ([1]=unsatisfactory, 2=poor, 3=satisfactory, 4=outstanding) in Appendix 2. The means of the above results by the two evaluators were calculated and recorded.

The primary outcome was the time taken to correctly complete the nerve block in the porcine meat model. The secondary outcomes included the following: (1) the MCQ score; (2) the score of drawing the anatomy; (3) the sonographic proficiency score; (4) the nerve recognition score; (5) the total score of every participant in the four live human model stations; (6) the cumulative score of errors; and (7) the worst sonographic image quality of the target nerve achieved.

## Statistical analysis

### *Sample size estimation*

Previous studies reported the mean length of time to perform the tasks at 37.63 seconds for simulation training vs. 93.83 seconds for nonsimulation training [19]. With the significance and power set at 0.05 (two-sided) and 90%, respectively, the sample size required to detect differences was 14. Considering a drop-out rate of approximately 25%, we planned to enroll 20 trainees. The sample size calculation was performed with PASS 11.0 software (Stata Corp. LP, College Station, TX).

### *Data analysis*

Normally distributed continuous variables are expressed as the mean ± SD and were compared using a two-tailed Student's t-test. Nonnormally distributed continuous variables and ordinal data are expressed as the median (interquartile range) and were analyzed using the Mann-Whitney U test. Categorical variables were expressed as case numbers and were analyzed by Chi-square or Fisher's exact test. A two-sided P value of less than 0.05 was regarded as statistically significant. All statistical analyses were performed with SPSS statistical package version 25.0 (IBM Corp. Armonk, NY, USA).

# Result

Twenty-two anesthesia residents were screened for eligibility: two residents were excluded for personal reasons, and twenty residents ultimately gave consent and were entered into the randomized study (Fig. 3). There were no significant differences in the characteristics of these residents between the WG and the CG (Table 1).

Table 1
Demographic data

| | Control group (n = 10) | Workshop group (n = 10) | P value |
|---|---|---|---|
| Age, years | 27.1 ± 2.8 | 28.2 ± 1.6 | 0.254 |
| Gender | | | |
| Male | 3 | 3 | > 0.999 |
| Female | 7 | 7 | |
| Handedness | | | > 0.999 |
| Left | 1 | 1 | |
| Right | 9 | 9 | |
| Education | | | 0.238 |
| M.D. | 8 | 6 | |
| M.M. | 2 | 4 | |
| Years on clinical rotation periods in anesthesiology | | | 0.785 |
| 3 | 3 | 2 | |
| 4 | 3 | 2 | |
| ≥ 5 | 4 | 6 | |
| Previous experience of ultrasound-guided vascular access | | | |
| ≤ 10 | 0 | 3 | 0.167 |
| 10–50 | 8 | 7 | |
| ≥ 50 | 2 | 0 | |
| The results are presented as the mean ± standard deviation or number. | | | |

The simulation-based training significantly reduced the time taken to correctly complete the target injection in the porcine meat models for participants in the WG compared with the CG (183.9 seconds ± 44.8 seconds vs. 239.6 seconds ± 64.2 seconds, P = 0.037) (Table 2). The total cumulative score of errors for trainees was significantly lower in the WG than in the CG (3.8 [3.0, 7.8] vs. 9.5 [6.9, 18.5], P = 0.007), as well as the individual error 6 and error 7 scores (0.3 [0.0, 1.0] vs. 2.3 [1.3, 3.9], P = 0.005; 0.0 [0.0, 1.0] vs. 2.3 [1.0, 3.0], P = 0.020). The other individual error scores were comparable between groups (P > 0.05) (Table 2).

Table 2
Effectiveness outcomes

| | Control group (n = 10) | Workshop group (n = 10) | Estimated effects (95% CI) [a] | P value |
|---|---|---|---|---|
| Primary outcome | | | | |
| Time taken, s | 239.6 ± 64.2 | 183.9 ± 44.8 | Mean D=-55.8 (-107.7, -3.7) | **0.037** |
| Secondary outcomes | | | | |
| MCQ | 39.3 ± 6.7 | 40.6 ± 7.9 | Mean D = 1.3 (-5.6, 8.2) | 0.696 |
| Scores of drawing anatomy | | | | |
| Transverse abdominis plane block | 7.5 ± 1.0 | 7.3 ± 1.6 | Mean D=-0.2 (-1.4, 1.1) | 0.743 |
| Thoracic paravertebral block | 3.3 ± 1.5 | 3.7 ± 1.9 | Mean D = 0.4 (-1.2, 2.0) | 0.606 |
| Brachial plexus block | 12.4 ± 2.5 | 14.5 ± 2.1 | Mean D = 2.1 (0.0, 4.2) | 0.053 |
| Femoral nerve block | 7.3 ± 2.9 | 9.0 ± 2.0 | Mean D = 1.7 (-0.6, 4.0) | 0.145 |
| Sonographic proficiency scores | | | | |
| Transverse abdominis plane block | 7.0 ± 2.4 | 7.5 ± 2.1 | Mean D = 0.5 (-1.6, 2.6) | 0.620 |
| Thoracic paravertebral block | 2.9 ± 2.1 | 5.7 ± 1.6 | Mean D = 2.8 (1.1, 4.5) | **0.003** |
| Brachial plexus block | 7.5 ± 4.0 | 12.4 ± 3.0 | Mean D = 4.9 (1.6, 8.2) | **0.006** |
| Femoral nerve block | 7.0 ± 2.4 | 10.7 ± 1.2 | Mean D = 3.7 (2.0, 5.4) | **< 0.001** |

The results are presented as the mean ± standard deviation, median (interquartile range). MCQ, multiple choice questions.

Values are mean ± SD or median (interquartile range).

[a] Calculated as the workshop group vs. or minus the control group.

[b] Summation of scores of drawing anatomy, sonographic proficiency scores and nerve recognition scores.

[c] Summation of cumulative error scores, including error 1 to error 7.

| | Control group (n = 10) | Workshop group (n = 10) | Estimated effects (95% CI) [a] | P value |
|---|---|---|---|---|
| Nerve recognition scores | | | | |
| Brachial plexus block | 3.0 ± 2.4 | 4.6 ± 2.0 | Mean D = 1.6 (-0.5, 1.0) | 0.120 |
| Femoral nerve block | 1.7 ± 0.5 | 2.0 ± 0.0 | Mean D = 0.3 (0.0, 0.6) | 0.081 |
| Total score [b] | 59.6 ± 15.0 | 77.4 ± 10.4 | Mean D = 17.8 (5.7, 29.9) | **0.006** |
| Cumulative error scores | | | | |
| Error 1 | 0.5 (0.0, 0.8) | 0.0 (0.0, 0.0) | Median D=-0.5 (-0.5, 0.0) | 0.075 |
| Error 2 | 3.0 (2.0, 5.1) | 3.0 (2.0, 3.6) | Median D = 0.0 (-1.5, 1.0) | 0.684 |
| Error 3 | 0.3 (0.0, 2.3) | 0.0 (0.0, 0.6) | Median D = 0.0 (-1.0, 0.0) | 0.393 |
| Error 4 | 1.0 (0.0, 2.4) | 1.0 (0.4, 1.1) | Median D = 0.0 (-1.0, 1.0) | 0.912 |
| Error 5 | 1.3 (0.0, 2.3) | 0.0 (0.0, 1.0) | Median D=-0.75 (-2.0, 0.0) | 0.063 |
| Error 6 | 2.3 (1.3, 3.9) | 0.3 (0.0, 1.0) | Median D=-2.0 (-3.5, 0.5) | **0.002** |
| Error 7 | 2.3 (1.0, 3.0) | 0.0 (0.0, 1.0) | Median D=-2.0 (-2.5, -1.0) | **0.002** |
| Total error scores [c] | 9.5 (6.9, 18.5) | 3.8 (3.0, 7.8) | Median D=-4.5 (-12.5, -2.0) | **0.007** |
| Sonographic image quality score | 3.3 (2.5, 4.0) | 4.0 (3.0, 4.0) | Mean D = 0.3 (0.0, 1.5) | 0.280 |

The results are presented as the mean ± standard deviation, median (interquartile range). MCQ, multiple choice questions.

Values are mean ± SD or median (interquartile range).

[a] Calculated as the workshop group vs. or minus the control group.

[b] Summation of scores of drawing anatomy, sonographic proficiency scores and nerve recognition scores.

[c] Summation of cumulative error scores, including error 1 to error 7.

The sonographic proficiency scores of PVB, BPB and FNB scanning in live human models in the WG were significantly higher than those in the CG (5.7 ± 1.6 vs. 2.9 ± 2.1, $P = 0.003$; 12.4 ± 3.0 vs. 7.5 ± 4.0, $P = 0.006$; and 10.7 ± 1.2 vs. 7.0 ± 2.4, $P < 0.001$, respectively), as was the total sonographic proficiency scores of TAP, PVB, BPB, and FNB (77.4 ± 10.4 vs. 59.6 ± 15.0, $P = 0.006$) (Table 2). The scores for the MCQ, the drawing of the anatomy and the sonographic proficiency of TAP scanning, the nerve recognition of BPB and FNB in the live human models, and the worst sonographic image quality in porcine models were comparable between the two groups (Table 2).

# Discussion

We found that a simulation-based training program could improve ultrasound-guided nerve block skills in live human models and porcine meat models in senior anesthesia residents. This training program might be adopted as routine for residents prior to the regional anesthesia rotation.

The time taken to complete nerve blocks and the error scores in the porcine meat models were significantly lower in the WG compared with the CG. In our study, every trainee executed the UGRA procedures twice, resulting in an obviously longer time taken than what has been noted in previous single procedure reports [19]. In addition, considering that 2 trainees in the CG had good experience in previous ultrasound-guided procedures (Table 1), the true difference in the primary outcome between groups may be even more significant.

Our study demonstrated the important role of simulation-based training in gaining the technical skills of UGRA, as reported previously by Marhofer et al [20]. The direct implication of our results is that the workshops using live human models in this study helped anesthesia residents acquire competency in ultrasound image acquisition and interpretation on four routine nerve blocks that are widely used in clinical practice in our hospital. The results of the PVB, BPB and FNB scanning were very encouraging in our study. However, the TAP training appears to have been less effective. First, it is easier to learn TAP scanning than the other nerve blocks, since the ultrasound structure of TAP is easily acquired and recognized. Second, there might be sufficient clinical observations of TAP for senior residents, even though they did not perform the procedure themselves. In our center, ultrasound-guided TAP nerve blocks were more often performed in the operating room where the senior residents cared for the patients, while other nerve blocks were commonly conducted in the preparing room where anesthetic nurses cared for the patients.

We also used the simulated “nerve”-embedded porcine meat model in which Chuan and colleagues demonstrated a similar effect on the training of ultrasound scanning and needle guidance skills as the cadaveric sciatic nerve block model [10]. To mimic plane block in clinical practice, we used another model with fascial layers. Similar to a previous study [11], we found that the use of meat models allowed trainees to learn UGRA techniques effectively, including the ability to perform in-plane needle insertions and visualize the needle tip. The interdependence and interaction between different workshops might strengthen the learning by trainees. Accordingly, the combination of various teaching sessions highlighted in our study could make UGRA education and training more effective.

Many studies have indicated that deliberate practice and mastery learning approaches of procedural skills can ensure expert-level performance, particularly for routine procedures such as UGRA [21–24]. The trainees in the WG groups had more time to learn and practice in the one-to-one interactive simulation-based workshops than the trainees in the CG groups. Much more importantly, feedback was provided with skill adjustments during the workshops, which is the key step in the acquisition of clinical skills [25]. Therefore, the results of our study confirmed that workshops consisting of practices and feedback promoted trainee acquisition of UGRA skills.

We performed systematic assessments in this study using previous tools and simulated models for evaluation [10, 11, 21]. The level of knowledge on UGRA was evaluated by MCQ and an anatomy drawing score; the skills of acquisition and recognition of sonographic anatomy structure were assessed by the sonographic proficiency score; the skills associated with needle placement were evaluated by the time taken to complete an ultrasound-guided target injection in the porcine meat models, the cumulative score of errors and the worst sonographic image quality score. For anesthesia residents with more than 3 years of experience, the necessary competence of UGRA could be evaluated by these combined tools according to the objective scores. A traceable synchronized video recording system helped to evaluate the technique and skills of UGRA by two isolated assessors. These measures made the assessments reliable and accurate.

Some of the assessment outcomes were comparable between groups in our study, i.e., the results of the written examination may be explained by the same didactic lectures for all trainees and their previous ultrasound knowledge. During the UGRA procedures in the porcine meat models, some individual error scores (error 1 to error 5) were not significantly different between the two groups, but all of the results consistently demonstrated an advantage of the workshop group. Our results showed that some error scores (error 6 and error 7) were different between the two groups, while others (error 1 to error 5) were not. Error 6 and error 7 were about needle advancement and intraneural needle pass or injection, which are very important for clinical patient safety. These results emphasize the importance of simulation-based training programs.

There are several limitations of our study. First, in this single-center trial, not all participants were new to ultrasound-guided procedures; therefore, a resulting bias could not be excluded. However, we chose randomization within blocks of time on rotation to balance this bias at baseline. Second, we did not conduct observations of real clinical practice because of safety and ethical concerns. Future follow-up with practice-based observations would help us to examine skill acquisition and retention and to evaluate the long-term impacts of the intervention training. Third, the trainees were aware of the study group to which they were assigned, which could have influenced their preparation before the test. However, the assessors were blinded, and we performed many measures to guarantee that the assessors were blinded to the grouping. Fourth, we did not conduct pretesting for participants on UGRA knowledge and skills; the baseline performance of trainees between the two groups might therefore be a confounding factor, although the impact of this factor could be improved by strict randomization. Finally, we did not use validated assessment scales of the TAP, PVB and FNB. Nonetheless, all these evaluation tools were extrapolated from relative forms of brachial plexus block, which was previously validated by Barrington et al [25].

# Conclusions

Simulation-based training significantly reduced the time taken to complete target injection under ultrasound and the errors during the procedure; it also improved residents' sonographic proficiency of scanning and recognition of anatomical structures in live human models. Our study integrates a series of simulation-based systematic assessments into the UGRA training curriculum. The clinical competency of the participants in UGRA following simulation-based training needs further evaluation in the future.

# Abbreviations

**ASRA** = The American Society of Regional Anesthesia and Pain Medicine; **BPB** = brachial plexus block; **CVC** = venous catheterization; **ESRA** = the European Society of Regional Anesthesia and Pain Therapy Joint Committee; **FNB** = femoral nerve block; **MCQ** = multiple choice questions; **PVB** = thoracic paravertebral block; **TAP** = transverse abdominis plane block; **UGRA** = ultrasound-guided regional anesthesia.

# Declarations

### Ethics approval and consent to participate

The research protocol was approved by the Biomedical Research Ethics Committee of Peking University First Hospital (Number: 2019-222). All participating trainees signed written informed consent.

### Consent for publication

Not applicable.

### Availability of data and materials

The detailed datasets are available from the corresponding author upon reasonable request.

### Conflicts of interests

The authors declare no conflicts of interest.

### Funding

This work was supported by the Research Foundation for Standardized Training of Residents in Health Science Centers, Peking University (No. 2019ZP32).

### Authors' contributions

ZML, MD: This author designed the study, collected data, performed data analysis, and drafted and revised the manuscript.

HK, MD: This author performed teaching and training and helped collect data.

FZ, MD: This author performed teaching and training and helped collect data.

XL, MD: This author performed teaching and training and helped collect data.

DH, MD: This author performed teaching and training and helped collect data.

YTL, MD: This author performed teaching and training and helped collect data.

HZ, MD: This author conceived and designed the study, reviewed and analyzed data, and revised the manuscript. He is the primary investigator and corresponding author.

### Acknowledgments

We sincerely thank Drs. Fan Cui, Zhen-Zhen Xu, Zhao-ting Meng (Department of Anesthesiology, Peking University First Hospital) and MSc Xue-Ying Li (Department of Biostatistics, Peking University First Hospital) for their help during the conduct of the study.

We truly appreciate Huon Snelgrove (Department of Education and Development, St. George's University Hospitals NHS Foundation Trust, United Kingdom), consultant in medical education, for his constructive advice on this study and preparation of the manuscript.

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# Figures

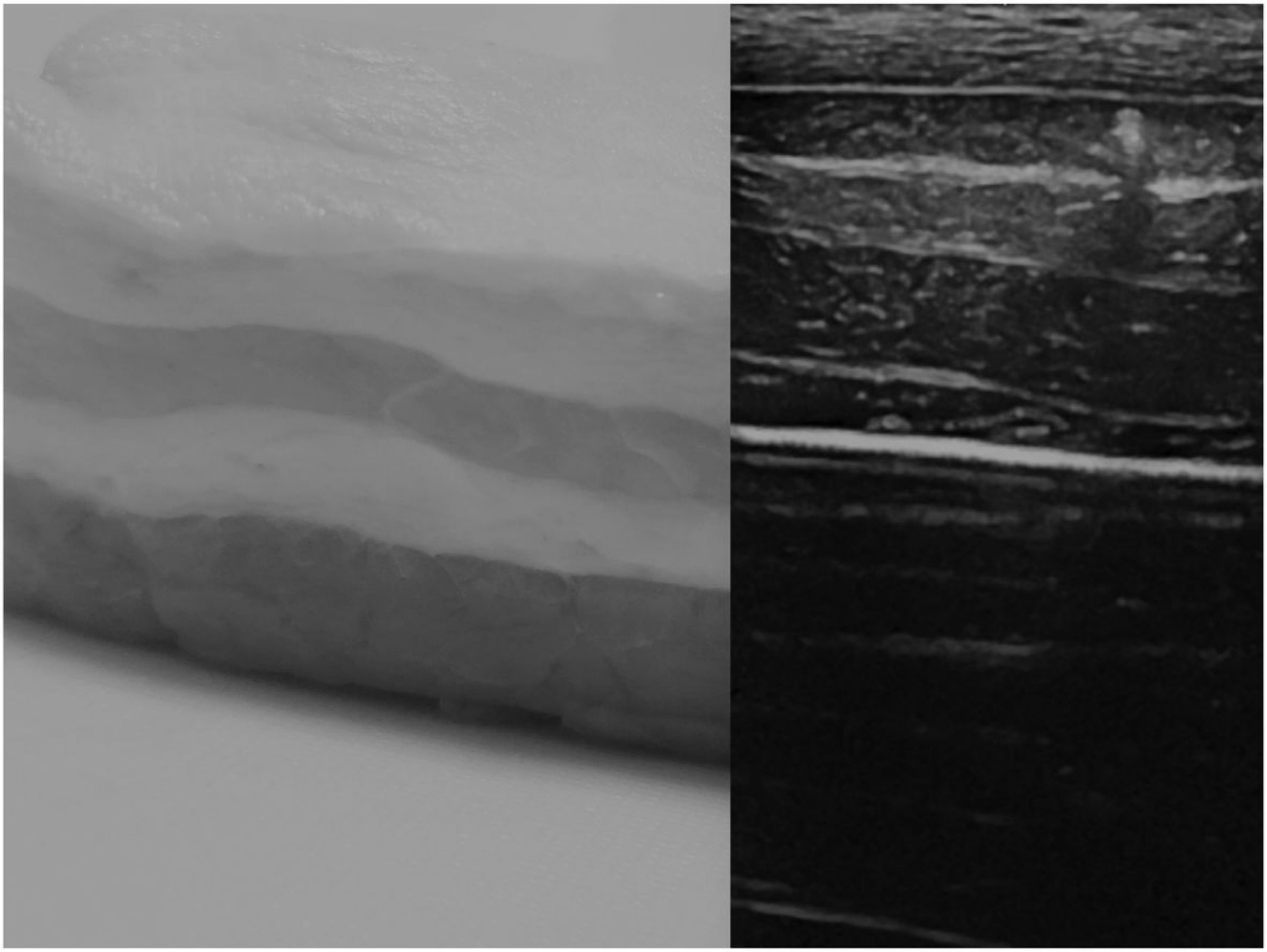


**Figure 1**

Model A: porcine meat containing fascial layers (Figure 1A), and the corresponding ultrasound image (Figure 1B) was obtained.

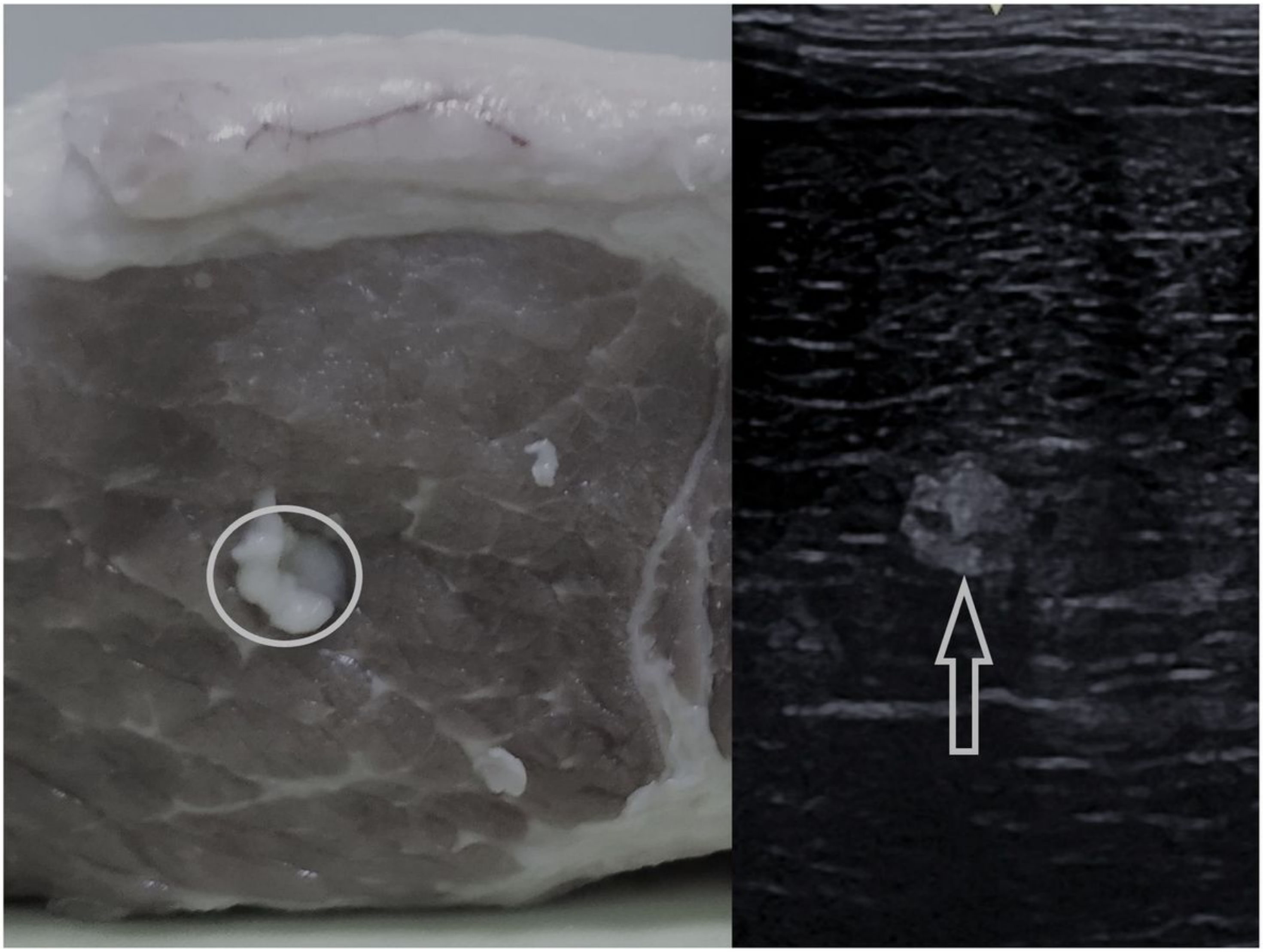
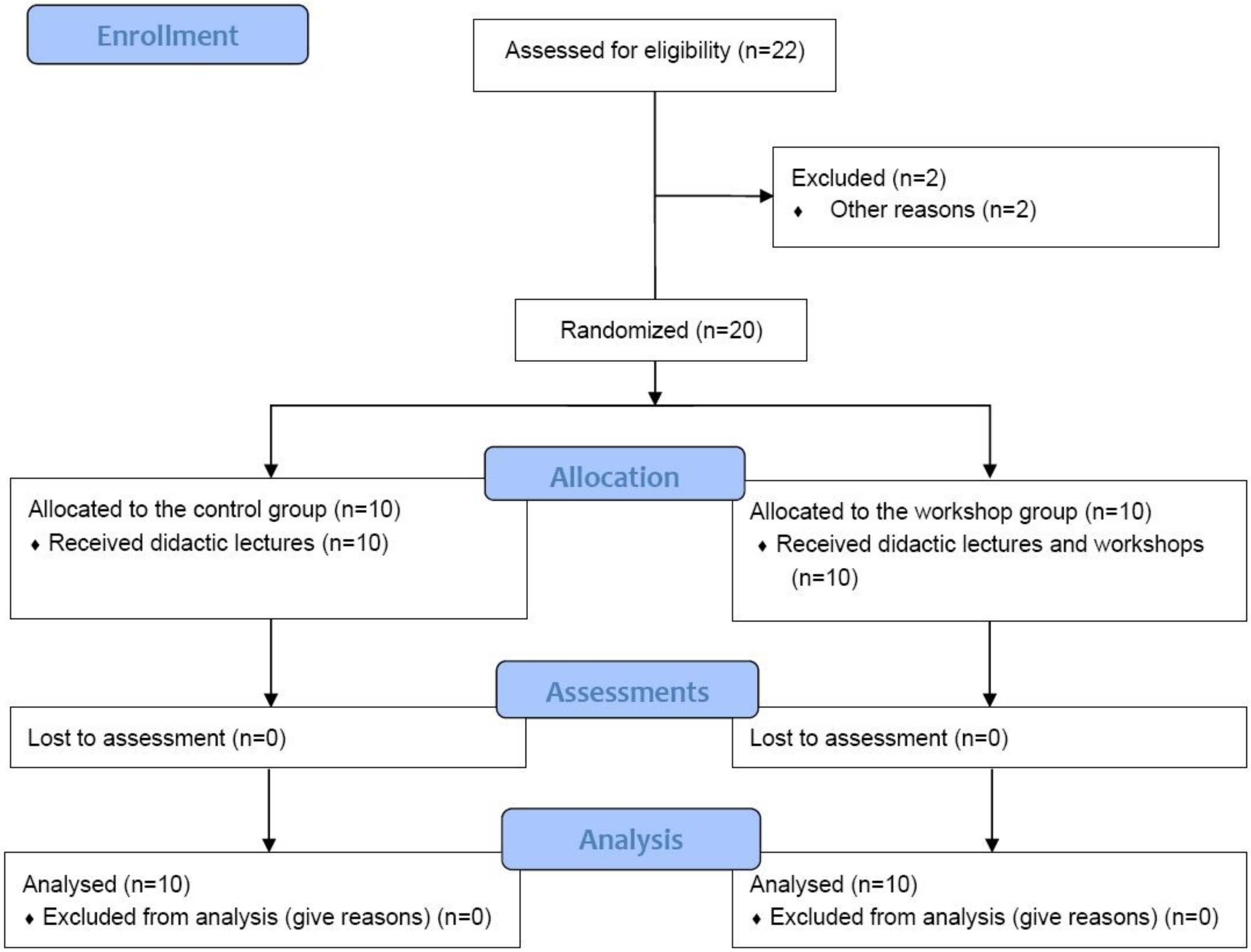


**Figure 2**

Model B: porcine meat with embedded bovine tendon (circled) (Figure 2A) and the corresponding ultrasound image (Figure 2B) obtained. The void arrow shows a hyperechoic structure mimicking the image of peripheral nerves in real patients.




## Figure 3

The study flowchart.


#### Figure 4

Photography of the assessment of ultrasound-guided target injection using porcine meat models with data records and a video camera.

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Appendix.docx
- CONSORT2010Checklist.doc