# A 3D multi-modal intelligent intervention system using electromagnetic navigation for real-time positioning and ultrasound images: a prospective randomized controlled trial

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**Background:** Anesthesia, nerve block, therapeutic injections, and biopsies all require an acupuncture intervention. However, traditional two-dimensional (2D) ultrasound-guided needle puncture is often challenging and therefore requires the use of three-dimensional (3D) ultrasound images to accurately identify and evaluate the patient's anatomical structure.

**Methods:** In this study, a 3D multi-modal intelligent intervention system using electromagnetic navigation for real-time positioning and ultrasound images was described. A total of 190 cases requiring puncture were randomly divided into control (conventional 2D ultrasound instrument) and experimental (novel 3D ultrasound imedis9000) groups. The advantages and disadvantages of the two puncture methods were prospectively analyzed in the 190 cases, and the feasibility of electromagnetic navigation real-time positioning was compared to ultrasound imaging.

**Results:** This study included 190 cases from two centers that required puncture treatment and were randomly assigned to the control (conventional 2D ultrasound instrument; n=95) or the experimental (novel 3D ultrasound imedis9000; n=95) groups. Percutaneous vascular puncture, percutaneous biopsy, percutaneous bile duct puncture, thoracic paravertebral nerve block, and sciatic nerve block operations were performed separately. The results indicated that the puncture time and number of trials in the experimental group were significantly lower than those in the control group. No significant difference was identified in the basic vital signs between the two groups before and after surgery. The success rate of the novel 3D ultrasound imedis9000 was 100%, and the success rate of the conventional 2D ultrasound instrument was 95.7%. Furthermore, the results also showed that the novel 3D ultrasound imedis9000 and the matching coaxial positioning channel puncture needle had low pain, good toughness and strength, and great convenience.

**Conclusions:** The new 3D multi-modal intelligent intervention system using electromagnetic navigation real-time positioning and ultrasound images has significant advantages compared with conventional 2D ultrasound in terms of puncture time, number of trials, operation difficulty, and convenience, and is worthy of further promotion and use in clinics.

**Trial Registration:** Beijing Municipal Drug Administration, 20190015.

**Keywords:** Three-dimensional ultrasound (3D ultrasound); ultrasound; real time positioning; prospective

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## Introduction

Some diagnostic and therapeutic clinical procedures involve needle intervention. The process needs precise needle positioning as well as tracking to increase the success rate of intervention and decrease the happen of adverse side effects (1,2). Ultrasonography is an inexpensive, real-time, as well as non-invasive image method that is extensively applied to direct needle insertion interference. However, imaging the target anatomy using traditional two-dimensional (2D) ultrasound is a frequent challenge because of requirements to make ultrasound probes align perfectly in order to contain the needle in the mirror plane. In addition, using a 2D ultrasound needs an exact interpretation about patient's three-dimensional (3D) anatomy according to a series of 2D ultrasound pictures, and success often relies on the physician's experience standard (3,4).

Newer approaches, such as 3D ultrasound, can guide needle insertion (5). 3D ultrasound can provide volumetric image result, which visualizes the needle as well as 3D anatomical constructions not necessary to make the ultrasound probe align perfectly. But the visibility of the needle using 3D ultrasound volume could be classified according to some elements (e.g., ultrasound speckle decreasing the quality of ultrasound result, the bright linear structures of the ultrasound volume similar to the needle, as well as reflection from the ultrasound beam for the needle in a distant direction from the probe) (6). The ways of automatic localization and tracking have been developed to inspect the needle in 3D ultrasound volumes in order to solve these problems. Currently, there are software and hardware-based methods that can enhance needle positioning and that track the needle in a 3D ultrasound volume. Hardware methods currently include the use of piezoelectric actuators to vibrate the needle, the use of a 3D power ultrasound to segment the vibrating bending needle, and the placement of a small ultrasonic sensor as a surgical tool to inspect the sound waves transferred in the period of the 3D ultrasound image process by moving needle as well as inspecting the decreased intensity change of ultrasound volume (7-10). This existing software-based methods include the use of principle component analysis (PCA) to detect the 3D ultrasound volume needle, as well as the use of radar transformation according to the radio frequency (RF) signal obtained by the 3D ultrasound probe to locate the needle (11,12). Real-time algorithms can also track the linear surgical instrument under the 3D ultrasound volume using Parallel Integral Projection (PIP) transformation to locate the thin needle inserted into the 3D ultrasound image (13-15).

The advantages of 3D imaging are well established in a variety of clinical settings. Albrecht *et al.* (16) studied the feasibility of real-time 3D ultrasound-guided biopsies and found that 3D ultrasound-guided biopsies is operated with multi-plane viewport or an unite of cross sections as well as rendered pictures. In distinguishing malignant from benign lesions, 3D ultrasound-induced biopsies produced thirty-five true positive consequences, twelve true negative consequences, and five false negative consequences. The sensitivity and distinctness of diagnosis in malignant tumors were 87.5% and 94.4%, separately. An *et al.* (17) compared the feasibility and efficiency of the 3D visual ablation planning system (3DVAPS) assisted by ultrasound-guided percutaneous microwave ablation (US-PMWA) with the conventional 2D hepatocellular carcinoma (HCC) plan (diameter >3 cm). Compared with the 2D planning group, the number of inserts, ablation time, ablation energy, and

 

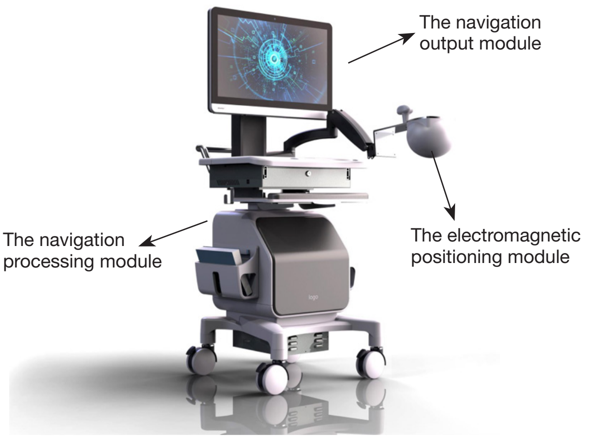


**Figure 1** Photo of the Novel 3D ultrasound imedis9000 instrument, which includes three main modules: the electromagnetic positioning module; the navigation processing module; and the navigation output module.

the success rate of the first ablation were higher in the 3D planning group. Recently, four-dimensional (4D) ultrasound has been used to generate patient-specific models in preparation for intervention and applied for real-time motion tracking, which is useful for local ablation (18).

Because of the localization of small Electromagnetic (EM) sensors appeared as a novel method, EM tracking requires no line-of-sight in a given EM field (19). The terminology "electromagnetic" is derived from a tracking phenomenon which electromagnets are used for producing varying or quasi-static magnetic fields and currents are generated of solenoids or fluxgate sensors set in the detectors (19). Zhou *et al.* (20) found out the application of EM systems of catheter tracking in prostate phantoms as well as explored an accuracy of 1.6±0.2 mm. Janssen *et al.* (21) presented a new way of chest brachytherapy which permits for catheter implantation on the basis of ultrasound-guided as well as EM navigated, and assessed the accuracy for EM catheter tracking in phantoms as well as chest cancer patients withstand chest brachytherapy pain. 3 chest brachytherapy patients have been cured by EM catheter tracking successfully. Catheter tracking typically needed no more than five minutes min with a mean accuracy of 1.7 ± 0.3 mm.

In this study, the electromagnetic navigation real-time positioning and B-ultrasonic image of the 3D multi-mode intelligent intervention system (novel 3D ultrasound imedis9000, Beijing Medis Medical Technology Co., Ltd., China) was invented and applied. A total of 190 cases that needed puncture interventions were randomly divided into control (conventional 2D ultrasound) and experimental (novel 3D ultrasound imedis9000) groups. The advantages and disadvantages of both puncture methods were prospectively studied in 95 cases in each group to evaluate the feasibility of electromagnetic navigation real-time positioning and the 3D multi-modal intelligent intervention system of ultrasound imaging. Furthermore, we introduced the characteristics of the novel 3D ultrasound imedis9000 and the matching coaxial positioning channel puncture needle. We present the following article in accordance with the CONSORT reporting checklist (available at https://atm.amegroups.com/article/view/10.21037/atm-21-5049/rc).

## Methods

### *Characteristics of novel 3D ultrasound imedis9000 and the matching coaxial positioning channel puncture needle*

Novel 3D ultrasound imedis9000 (Beijing Medis Medical Technology Co., Ltd., China) can be used for 3D scanning, volume data acquisition, processing, and image display. The device includes three main modules (1). The electromagnetic positioning module: the electromagnetic positioning module is connected to the ultrasonic imaging equipment and the interventional device to obtain the position and direction of the B-ultrasonic image generated by the B-ultrasonic imaging equipment and the position and direction of the interventional device (2). The navigation processing module: the navigation processing module is connected to B-ultrasonic imaging equipment and electromagnetic positioning module. The navigation image is formed according to the position and direction of the ultrasound image, the position and direction of the interventional device, and the interventional path (3). The navigation output module: the navigation output module is connected to the navigation processing module and outputs the navigation image according to the set display mode (*Figure 1*).

Novel 3D ultrasound imedis9000's screen display is compatible with a grayscale ultrasound and has suitable surgical brightness, which is in line with the doctor's surgical vision habits. The mechanical arm of the 3D multi-modal intelligent intervention ultrasound can be regulated in multiple degrees of freedom. In addition, the instrument can be sterilized directly and has excellent dust-proof performance (*Figure 1*). Furthermore, its ultrasound interface is compatible with mainstream ultrasound technologies.

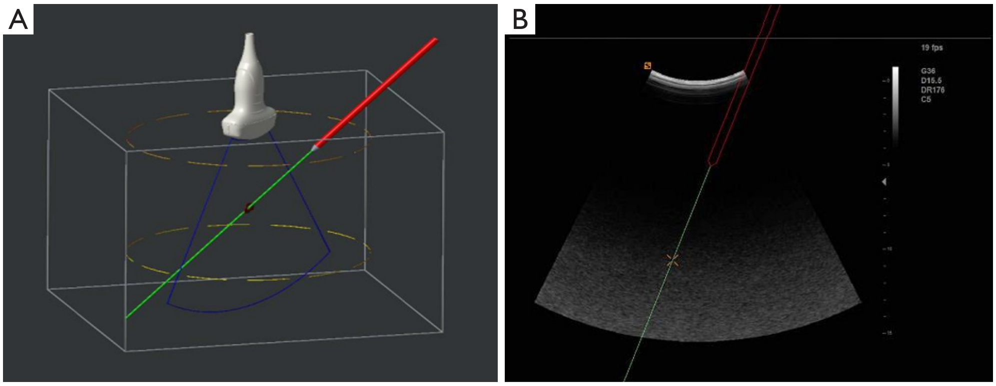


**Figure 2** Electromagnetic navigation real-time positioning and ultrasound images. The red line in each picture represents the puncture path, and the green cross represents the final part of the puncture.

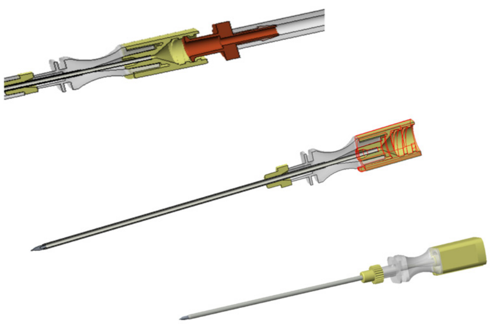

**Figure 3** Design of the coaxial positioning needle.

Compared with the conventional 2D ultrasound instrument, the novel 3D ultrasound imedis9000 has many advantages in a range of applications. The novel 3D ultrasound imedis9000 has a small footprint, high flexibility, and does not require complex setup and preoperative preparation (*Figure 1*). It supports a variety of surgeries (e.g., spinal and spinal space-occupying, nerve compression, and spinal degenerative variations). Also, since it does not rely on a large imaging instrument, it can provide imagery during minimally invasive day surgery on the spine. When using this 3D ultrasound, preoperative puncture angle design is no longer limited, the puncture path and needle tip position are monitored in real time during the operation, there are intraoperative intelligent reminders if lesion target deviation occurs and when the needle arrives at the lesion target, and the technology enables clear puncture path planning and intuitive real-time stereotactic positioning (*Figure 2*).

We synchronously matched the coaxial positioning channel puncture needle (*Figure 3*), which has three characteristics. First, the coating absorbs super slippery coating technology, which has less resistance, and feels painless under most conditions. Second, the material is imported stainless steel, which is tough and strong. This enables corrosion performance, biocompatibility, and consistency to better meet the needs of interventional systems. Third, a number of series and specifications of disposable access trocars have been designed and manufactured, covering biopsy puncture, anesthesia puncture, radiofrequency and microwave therapy, spinal foraminal puncture and other occasions, and mainstream interventional therapy consumables are used with precision. Based on the different needle types and specifications required by different surgeries, we set up a variety of needle types to facilitate more convenient use (*Table 1*).

### *Study design and setting*

The present prospective, double-center, randomized study was conducted on cases recruited from two centers (the Affiliated Hospital of Nantong University and Nanjing First Hospital, Nanjing Medical University). This study included 190 cases that needed puncture treatment, who were randomly divided into a control group (conventional 2D ultrasound instrument; n=95) and an experimental group (novel 3D ultrasound imedis9000; n=95). Percutaneous vascular puncture, percutaneous needle biopsy, percutaneous bile duct puncture, thoracic paravertebral nerve block, and sciatic nerve block were performed separately. The specific experimental design and the number of cases in each group are shown in

 

**Table 1** The specifications and models for coaxial positioning channel puncture needles

| Models | Specifications |
|---|---|
| MDS 16/75A | 16G ×75 |
| MDS 16/110A | 16G ×110 |
| MDS 16/150A | 16G ×150 |
| MDS 16/75B | 16G ×75 |
| MDS 16/110B | 16G ×110 |
| MDS 16/150B | 16G ×150 |
| MDS 17/75A | 17G ×75 |
| MDS 17/110A | 17G ×110 |
| MDS 17/150A | 17G ×150 |
| MDS 17/75B | 17G ×75 |
| MDS 17/110B | 17G ×110 |
| MDS 17/150B | 17G ×150 |
| MDS 18/75A | 18G ×75 |
| MDS 18/110A | 18G ×110 |
| MDS 18/150A | 18G ×150 |
| MDS 18/75B | 18G ×75 |
| MDS 18/110B | 18G ×110 |
| MDS 18/150B | 18G ×150 |
| MDS 19/75B | 19G ×75 |
| MDS 19/110B | 19G ×110 |
| MDS 19/150B | 19G ×150 |
| MDS 20/75B | 20G ×75 |
| MDS 20/110B | 20G ×110 |
| MDS 20/150B | 20G ×150 |

MDS, Beijing Medis Medical Technology Co., Ltd.

*Figure 4*.

### *Ethical approval and informed consent*

This study was approved by the Human Ethics Committee of the Affiliated Hospital of Nantong University (No. 2018-Q062) and Nanjing First Hospital, Nanjing Medical University (No. QX20181102-02), and the participants gave informed consent before taking part. The study conformed to the provisions of Declaration of Helsinki (2013 revised), and results were written and studied anonymously for privacy protection of patients.

### *Inclusion criteria*

These included patients met the following criteria: (I) patients with surgical pointers of percutaneous vascular puncture, percutaneous needle biopsy, percutaneous bile duct puncture, thoracic paravertebral nerve block, and sciatic nerve block; and (II) patients who agreed to participate in this clinical trial.

### *Exclusion criteria*

Patients encountered any following standards were eliminated in the paper: (I) patients who did not meet the puncture requirements; (II) patients with major organ dysfunction and intolerance to puncture; and (III) patients with advanced age, poor general condition, or limited life expectancy.

### *Interventions*

Novel 3D ultrasound imedis9000 was used for 3D scanning and image acquisition. A conventional 2D ultrasound instrument (Siemens, Germany) was used in the control group. The puncture and nerve block surgeries mentioned above were performed separately, and the puncture time, number of trials, vital signs variations, and success rate were assessed. All biopsies and nerve blocks were carried out with local anesthesia (lidocaine 1%). Three experienced chief physicians participated in each operation.

### *Perioperative treatment for enrolled patients*

The preoperative essential vital signs (e.g., respiration, pulse, systolic and diastolic blood pressure) of the 190 patients were recorded. In addition, preoperative blood routine indicators (including white blood cells, hemoglobin, and platelets) and prothrombin time requirements were also recorded.

### *Implementation*

The Affiliated Hospital of Nantong University and Nanjing First Hospital, Nanjing Medical University registered the participants, and assigned them to the intervention.

 

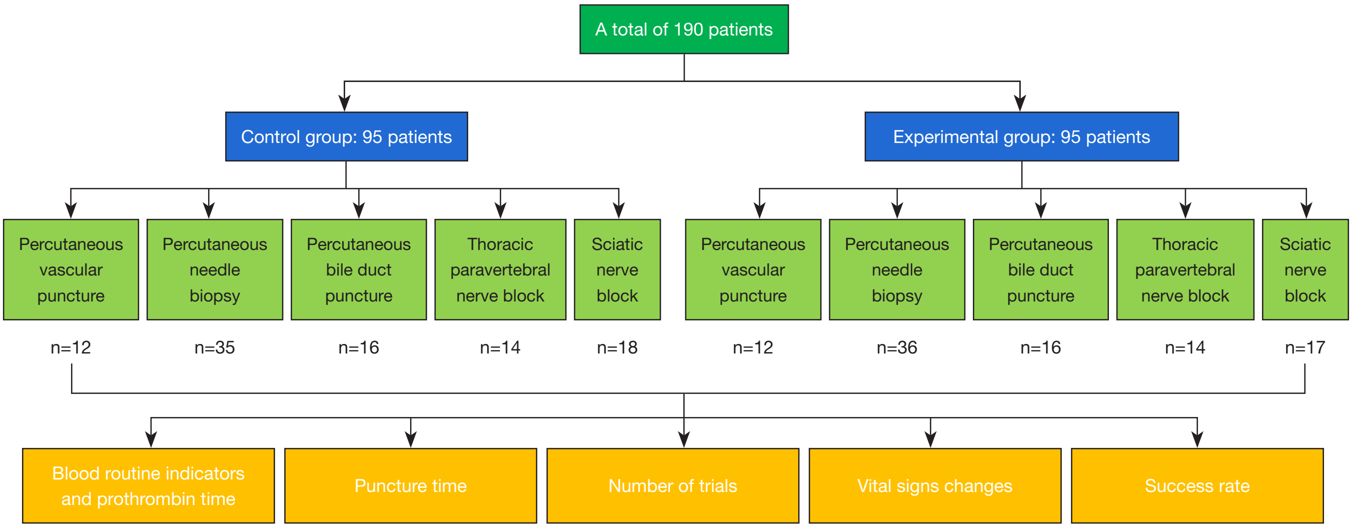


**Figure 4** The flow chart designed for this study. The puncture surgery and nerve block surgery mentioned above were performed separately. The puncture time, number of trials, basic vital signs, and success rate were evaluated.

### *Assignment of interventions for blinding*

The trial was not double-blind, and the protocol was known to both patients and doctors.

### *Adverse events*

All serious adverse events (SAEs) that occurred between the signing of the informed consent form and the completion of the trial were written and declared particularly no more than a whole day. Next, we reported SAEs to the ethics committee in the unit. SAEs were considered as adverse medical incidents related to or not related to operations. In the research, data supervision committee supervised the safety data with an unblinded method, as same as Standard Operation Procedures for Clinical Trials. The enrolled sick persons received the optimal possible treatment of complications that arose.

### *Monitoring and quality assurance*

The research possesses a Data and Safety Monitoring Committee (DSMC), with specified and co-operative members. Oversight committee is composed of senior professors in the aspect of imaging, data management, data detectors, medical ethics scholars, as well as a methodological team. The DSMC will have free evaluate to study data, supervisor, audit reports, as well as other recording activities associated with quality assurance.

### *Definition of operation success and failure*

Puncture surgery was considered successful when the needle accurately reached the target location and obtained the doctor's desired sample. If the location was not reached or the sample was not obtained, the surgery was considered a failure. Nerve block surgery was considered successful when the needle accurately arrived at the target location and injected the relevant drugs. If the location was not reached or the injection of drugs was not performed, the surgery was considered a failure.

### *Sample size*

This study included 190 cases that needed puncture treatment, and were randomly divided into a control group (conventional 2D ultrasound instrument; n=95) and an experimental group (novel 3D ultrasound imedis9000; n=95).

### *Statistical analysis*

We carried out the analyses largely based on GraphPad Prism 8.0 (GraphPad, USA), and a P value <0.05 was considered statistically significant. We compared continuous information based on an individual *t*-experiment in the two groups.

 

**Table 2** Comparison of baseline data between the two groups

| Group | Gender | | Age (years), $\bar{x}$±s |
|---|---|---|---|
| | Male | Female | |
| Control group (n=95) | 37 | 58 | 53.33±12.93 |
| Experimental group (n=95) | 38 | 57 | 52.64±12.81 |
| P | 0.5 | | 0.3664 |

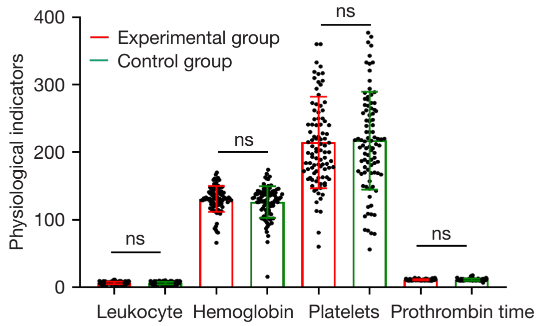


**Figure 5** Preoperative blood routine indicators (including leukocyte, hemoglobin, platelets) and prothrombin time of the 190 patients enrolled in both groups were analyzed. ns indicates no statistically significant difference.

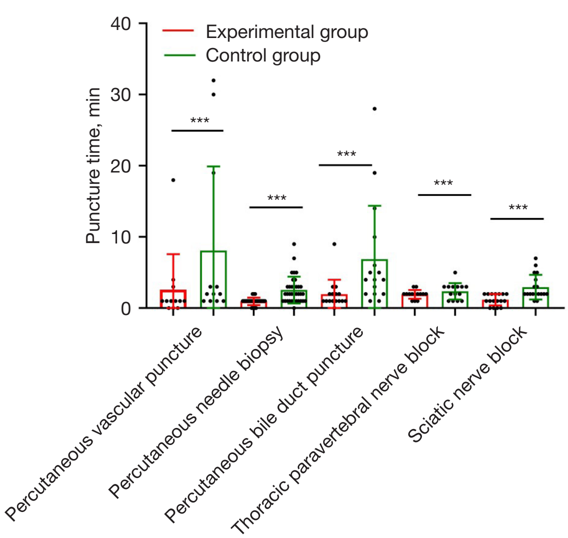


**Figure 6** The puncture time in each group with different operations was analyzed. ***, P<0.001.

### *Patient involvement*

The patients play a key role in the layout, gathering, studying, explaining data and declaring as well as making a decision to publish in this research.

### *Dissemination plans*

The data will be submitted in high quality peer-reviewed periodical upon completion of this research.

### *Trial status*

This trial was completed at the Affiliated Hospital of Nantong University and Nanjing First Hospital, Nanjing Medical University. This trial has been registered in the Beijing Municipal Drug Administration (No. 20190015) and the current status of the trial is finished.

### *Clinical trial results*

There were 37 males and 58 females in the control group, aged 22–75 years, with an average age of 53.33±12.93 years. There was 38 male and 57 females in the experimental group, aged 25–74 years, with an average age of 52.64±12.81 years. There was no significant difference in the baseline data between the two groups (P>0.05; *Table 2*).

Based on our study design, we analyzed the preoperative blood routine indicators (including leukocyte, hemoglobin, platelets) and prothrombin time of the 190 cases enrolled in the experimental as well as control parts, and found no distinct difference between 2 groups (*Figure 5*). Next, we analyzed the data of different operation methods and found that, compared with the control group, the puncture time of the experimental group was significantly shortened (*Figure 6*), and the number of trials was also significantly reduced (*Figure 7*). Differences in the basic vital signs (e.g., respiration, pulse, systolic blood pressure and diastolic blood pressure) were assessed before and after the two methods, and the absolute value was statistically analyzed. The results revealed that the mentioned basic vital signs were not significantly different between the two groups before and after surgery (*Figure 8*). The puncture success rate of the novel 3D ultrasound imedis9000 was 100% (95/95), and that of the 2D ultrasound instrument puncture was 95.7% (91/95). In addition, we collected photographs of each operation and showed images of each type of puncture procedure for the 3D ultrasound station (*Figures 9-14*). The adoption of the novel 3D ultrasound imedis9000 clearly defined the puncture path planning and intuitive real-time stereoscopic positioning, greatly improved the success rate of puncture, and shortened the operation time.

 

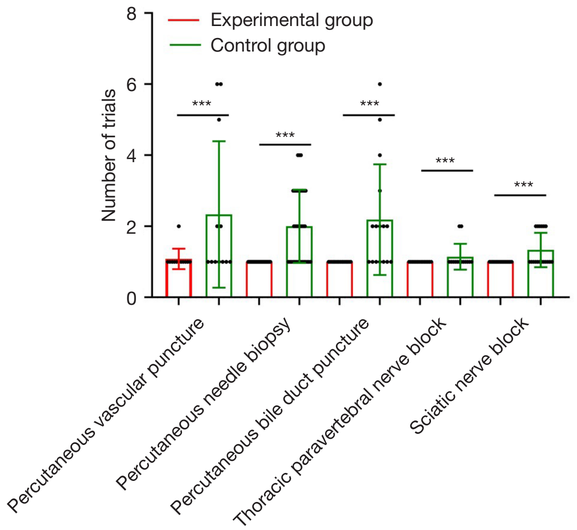


**Figure 7** The number of trials in each group with different operations was analyzed. ***, P<0.001.

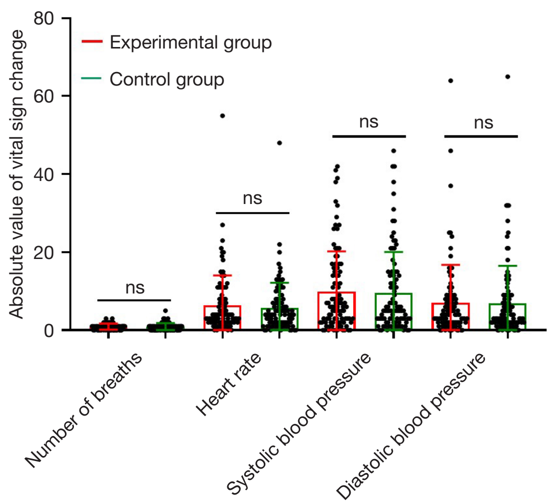


**Figure 8** Differences in the basic vital signs (such as respiration, pulse, systolic blood pressure and diastolic blood pressure) were evaluated before and after the two methods, and the absolute value was statistically analyzed between the two groups. ns indicates no statistically significant difference.

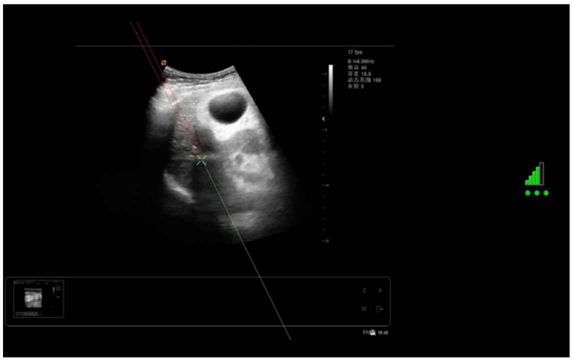

**Figure 9** Novel 3D ultrasound image of percutaneous vascular puncture (hepatic vein portal vein). The red line in each picture represents the puncture path, and the green cross represents the final part of the puncture. The green box on the right represents the electromagnetic signal.

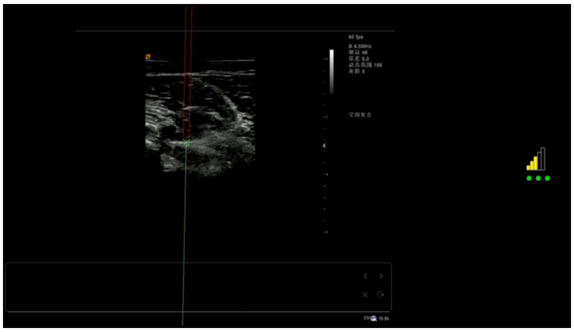

**Figure 10** Novel 3D ultrasound image of a percutaneous vascular puncture (popliteal vein).

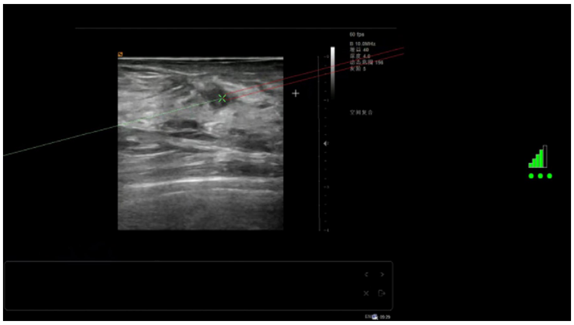

**Figure 11** Novel 3D ultrasound image of a percutaneous biopsy puncture (breast).

## Discussion

In recent years, ultrasound imaging has become a useful way of diagnostic process for all areas of medical science. Its superiority compared with other image modalities, like computed tomography (CT) or magnetic resonance imaging (MRI), lies in its alternating use, liquidity, and inexpensive. Ultrasound equipment developed from ordinary A-mode systems since 1960s to the 3D real-time systems that are currently available (22). As this evolution

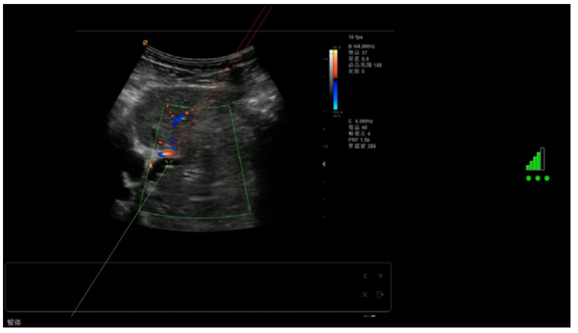

**Figure 12** Novel 3D ultrasound image of a percutaneous bile duct puncture.

**Figure 13** Novel 3D ultrasound image of a thoracic paravertebral nerve block.

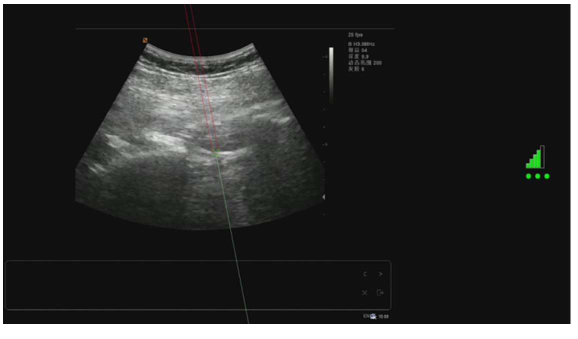

**Figure 14** Novel 3D ultrasound image of a sciatic nerve block.

continues, ultrasound is being increasingly used for intraoperative monitoring and guidance, such as myocardial biopsy and intracardiac catheter placement. Similarly, in minimally invasive surgery, ultrasound has become a valuable tool for image-based guidance, as the surgeon's field of vision is limited by the small incision (23,24). As 3D ultrasound technology continues to develop, it has become possible to extend the 3D ultrasound probes with position sensors (25). The combination of 3D ultrasound probes and electromagnetic sensors has many potential applications. One application is to improve image quality by fusing numerous captures from multiple directions. In addition, navigation of minimally invasive interventions is improved through connecting the site sensors to 3D probes and/or instruments.

In our study, a novel 3D ultrasound imedis9000 was invented and applied. This combined three modules: an electromagnetic positioning module, a navigation processing module, and a navigation output module. Compared with the conventional 2D ultrasound instrument, the novel 3D ultrasound imedis9000 has many advantages in a range of applications, such as its high flexibility and simple preoperative preparation. Preoperative puncture angle design is no longer limited, intraoperative puncture path and needle tip position are monitored in real time, and intraoperative intelligent reminders of lesion deviation and lesion arrival is provided. Previous studies have also reported that positioning accuracy can be improved with dynamic navigation technology based on electromagnetic tracking ultrasound in clinical interventional therapy. Paolucci *et al.* (26) proposed a navigation method based on an electromagnetic tracking laparoscopic ultrasound (ELUS) that permits exact and effective targeted liver tumors in the laparoscopic model. The focus on dynamic and tumor-targeted guidance techniques that rely on intraoperative image to avoid underlying inaccuracies for organ transformation has led to an effective and user-friendly laparoscopic liver tumor ablation technique. Hatt *et al.* (27) proposed a novel imaging blending system of targeted according to catheter delivery in therapeutic agents. These system records RT 3D echocardiography, MR, as well as X-ray and electromagnetic sensor tracking in the flexible frame. All systems calibration as well as registration could be verified, and the target registration error was found to be on more than 5 mm at the worst situation. The injection accuracy could be verified for the moved cardiac injection body model, with a targeting accuracy range of 0.57 to 3.81 mm. Clinical feasibility could be illustrated by *in vivo* pig tests in which the injection was successfully delivered to the target area of the heart. Lavallée *et al.* (28) reported that the EM system provided a quick and exact solution of automatic catheter reconstruction with EM technology. In their research, the test run as well as operation assessment in Philips Disease Management Solutions' new RT prostate large dose rate brachytherapy research system (USA) integrated with EM was carried out prior to its clinical integration, and proved to be stabilized, exact, and accurate.

 

Complete integration EM tracking technique paves the way for automated catheter reestablishment as well as dynamic reprogramming.

This study included 190 cases from two centers that required puncture treatment, and were randomly distributed to the control or the test groups. We analyzed the preoperative blood routine indicators and prothrombin time of the 190 cases enrolled in experiment as well as control parts, and found no significant difference between the two groups, which indicated that there was no obvious personal bias in this study. No evident distinction was identified in the basic vital signs between two parts before and after surgery, suggesting that the two surgical methods had no significant effect on the cases' vital signs. The puncture time and number of trials of the experimental group were significantly lower than those of the control group. The success rate of the novel 3D ultrasound imedis9000 was 100%, and that of the conventional 2D ultrasound instrument was 95.7%. Our study confirmed the feasibility, convenience, and safety of the novel 3D ultrasound imedis9000.

One of the largest advantages of novel 3D ultrasound imedis9000 is that it can enable surgeons to accurately perform a nerve block. The peripheral nerve is a intricacy, highly heterogeneous structure with many micro anatomical structure from roots to the terminal branches. Ultrasound, as a nerve localization technology, allows a particular and person-specific test for anatomy covered in the peripheral nerve block. A medical ultrasound exploits sound waves in the frequency range of 3–15 MHz. Nerve visualization requires the use of probes with the ability to produce ultrasound at 10–15 MHz. Ultrasound at the mentioned frequencies presents prominent spatial resolution, which enables discrimination of the nerve architecture during surgery. Anatomical site and the quantity of connective tissue in nerves are related to the ultrasonographic appearance of nerves (29). It has been reported that an introduction about the challenges in imaging interpretation and common image-related anomalies previously (30,31). However, our technical positioning is more precise, and the operation is more convenient. We have also designed and manufactured multiple series and specifications of disposable access trocars, covering biopsy puncture, anesthesia puncture, radiofrequency and microwave therapy, and spinal foraminal puncture, and the precise use of consumables significantly mitigates the suffering of cases.

This study had certain limitations that should be noted. Firstly, our research centers are relatively small, and there are only two research centers. We look forward to including more research centers in future studies. Secondly, the types of operations need to be increased, and more novel 3D ultrasound instruments (e.g., microwave ablation) need to be used to test their effectiveness. Thirdly, more cases should be surveyed to assess satisfaction and follow-up regarding postoperative complications.

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## Footnote

*Reporting Checklist:* The authors have completed the CONSORT reporting checklist. Available at https://atm.amegroups.com/article/view/10.21037/atm-21-5049/rc

*Trial Protocol:* Available at https://atm.amegroups.com/article/view/10.21037/atm-21-5049/tp

*Data Sharing Statement:* Available at https://atm.amegroups.com/article/view/10.21037/atm-21-5049/dss

*Peer Review File:* Available at https://atm.amegroups.com/article/view/10.21037/atm-21-5049/prf

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at https://atm.amegroups.com/article/view/10.21037/atm-21-5049/coif). XW serves as an Editor-in-Chief of *Annals of Translational Medicine* from August 2019 to July 2024. MH is the president of Beijing Medis Medical Technology Co., Ltd. and provided the novel 3D ultrasound imedis9000 system for this clinical trial free of charge. No financial conflict of interest exists between Beijing Medis Medical Technology Co., Ltd. and hospitals. The other authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study conformed to the provisions of the Declaration of Helsinki (as revised in 2013). This study was approved by the Human Ethics Committee of the Affiliated Hospital of Nantong University (No. 2018-Q062) and Nanjing First Hospital, Nanjing Medical University (No. QX20181102-02). The participants gave informed consent before taking part. All data were recorded and analyzed anonymously to protect patient privacy.



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