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# Safety and efficacy of cerebral robot assisted angiography: randomized comparison of robotic versus manual procedures

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## ABSTRACT

**Background** While robotic assisted technology has advanced in cardiovascular interventions, neurovascular applications still lack a robotic system. To assess the safety and efficacy of novel robotic systems designed for cerebral angiography, we conducted a multicenter, randomized controlled non-inferiority trial.

**Methods** 130 patients were recruited who received cerebral angiography in four centers. After identifying the target vessels, patients were randomly allocated to an experimental group for robotic procedures and a control group for manual procedures in a 1:1 ratio. Clinical success rate, technical success rate, overall surgery time, pre-puncture set-up time, puncture-to-unsheathed time, mean catheterization time per target vessel, X-ray fluoroscopy time, and primary operator's radiation dose were compared. The safety endpoints were incidence of perioperative vascular injuries, any adverse events, and device malfunctions.

**Results** 64 patients were assigned to the experimental group and 66 to the control group. Both groups achieved 100% clinical success and a 100% technical success. Significantly, the primary operator's radiation dose in the robotic group was lower than that in the manual group (1.67±3.49 µSv vs 43.63±38.95 µSv, P<0.001). The puncture-to-unsheathed time (P=0.882), mean catheterization time per target vessel (P=0.247), and fluoroscopy time (P=0.701) were comparable. The pre-puncture set-up time in the robotic group was longer (P<0.001), attributed to prolonged robotic instrument set-up. No robot related adverse events were observed.

**Conclusion** The trial showed that the robotic system was safe and effective for assisting cerebral angiography, notably reducing primary operators' radiation exposure.

**Trial registration number** ClinicalTrials.gov NCT05778214.

## INTRODUCTION

Cardiovascular interventional robots evolved through multiple generations over the past few years.[1] The safety and efficacy of robotics in both simple and complex percutaneous coronary interventions have been demonstrated in multicenter trials.[2 3] Despite several studies demonstrating the feasibility of robotic systems in neurointervention, significant technical challenges (eg, managing longer access paths and achieving submillimeter precision) must be resolved before these systems can effectively reduce occupational hazards for clinicians and enhance procedural safety.[4]

In response to these challenges, we have developed a new generation of a robotic system specifically for neurointervention, the PANVIS-A robotic system (Shenzhen Institute of Advanced Biomedical Robot, Guangdong Province, China), which incorporates numerous design enhancements and functional optimizations compared with previous cardiovascular or peripheral vascular interventional robots.[5–8] The PANVIS-A robot features completely different control sticks, named catheter on finger design (figure 1). Unlike the console controllers of previous robots that resembled game joysticks, the novel control sticks are positioned horizontally, simulating the spatial arrangement of guidewires and catheters on the procedural table, which is more in line with the operating habits of interventional physicians for catheters and guidewires.

In addition, the novel robot is equipped with two delivery devices using clamping device mechanisms, enabling simultaneous and independent control of both devices: one guidewire and one catheter. The guidewire delivery device mimics the manual pinch and push motion of a physician's thumb and index finger. Two clamps alternately open/close and move axially to achieve unlimited catheter travel distance, constrained only by catheter length. Dual clamps of the guidewire delivery device can simulate the twisting motion of human fingers (thumb–index coordination) to rotate the guidewire. They allow for precise millimeter scale adjustments for advancing, retracting, rotating, or executing complex combined movements (such as simultaneous advancement and rotation) to deliver the catheter and guidewire. The system is compatible with a variety of 5 F angiographic catheters or 6 F guiding catheters (up to 125 cm), including pigtail catheters, single curve catheters, Simo catheters, MPA1 catheters, Hunter catheters, and 0.035-inch guidewires (up to 260 cm). The system is capable of long distance delivery of guidewires and catheters from the femoral artery to the cavernous segment of the internal carotid artery. To evaluate the safety and efficacy of the PANVIS-A system in cerebral angiography, we designed this randomized controlled trial (RCT) comparing the robotic assisted procedure with manual procedures.

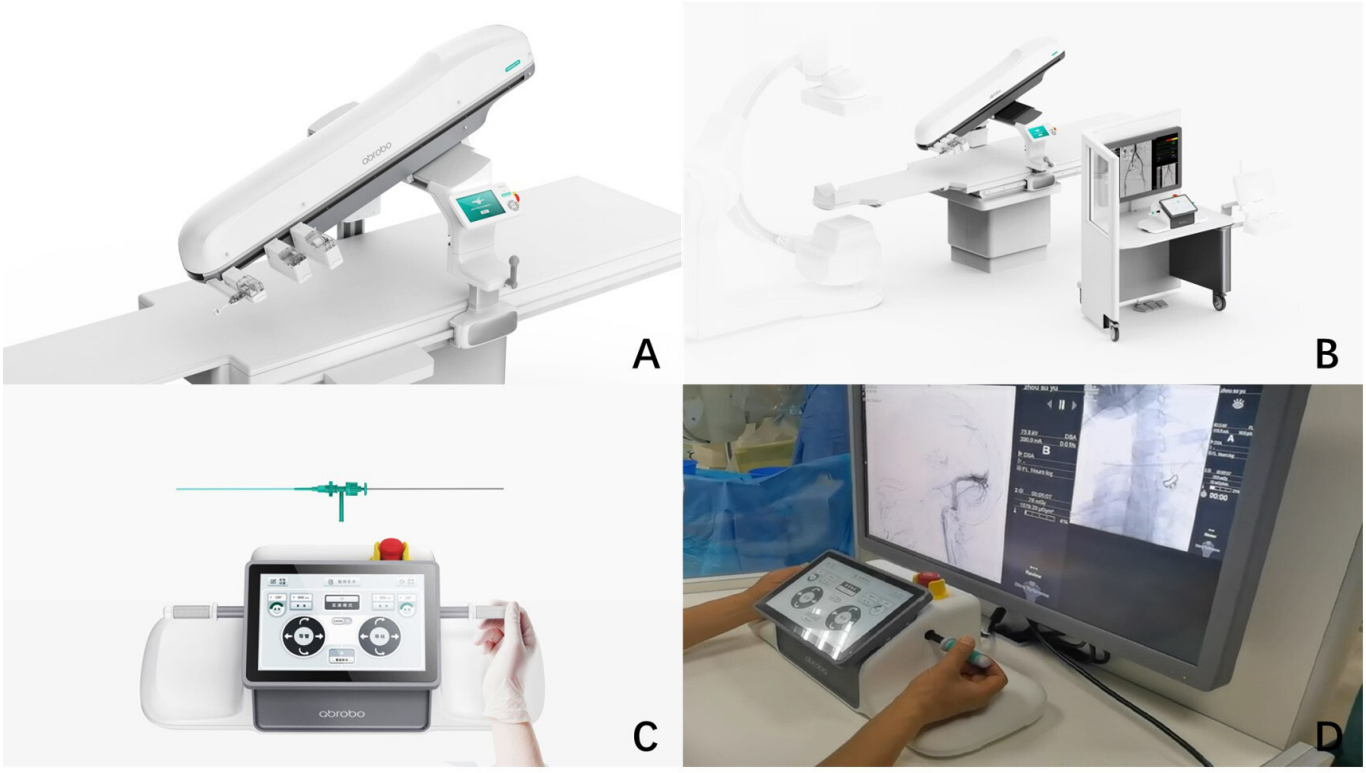


**Figure 1** Basic structure of PANVIS-A robotic system (Shenzhen Institute of Advanced Biomedical Robot, Guangdong Province, China) and practical application scenario. (A) The robot operates in a master–slave mode, with a master and a slave manipulator on the DSA table. (B) Three delivery devices enable complex movements of one guidewire and one catheter. (C) The "catheter on finger" supports composite motions, such as rotational delivery and rotational retraction, with various motion modes for precise and effective control of the guidewire and catheter. (D) The surgeon's intraoperative manipulation scenario.

## METHODS

### Study design and patients

This trial was designed as a prospective, multicenter, randomized controlled non-inferiority study, with the aim of recruiting 130 patients who required cerebral angiography in four centers (ClinicalTrials.gov NCT05778214). To ensure patient safety, operators were required to have ≥5 years of experience in cerebral angiography. All operators underwent two dedicated simulation sessions before the clinical procedures (silicone vascular model training and live porcine model training) to familiarize operators with the robotic system assembly and operating steps. The objective of live porcine model training was to simulate clinical scenarios, including sterile techniques, all steps of angiography, emergency management, and human–robot transition. The operator completed selective catheterization of bilateral internal carotid arteries (ICAs) and bilateral vertebral arteries (VAs) and simulated implementing emergency protocols (robotic system emergency stop and rapid conversion to manual operation). The protocol was approved by the respective ethics committee of each participating site.

In accordance with the clinical indications in the Chinese expert consensus on operation specification of cerebral angiography,[9] patients participating in this clinical trial were required to fulfill the following criteria: (1) aged 18–85 years; (2) scheduled to undergo transfemoral approach cerebral angiography because of cerebrovascular disease; and (3) voluntarily participated in this trial and signed the informed consent form. Prospective consecutive recruitment was encouraged, and subjects were excluded if there was (1) unwillingness of the subject to provide informed consent, (2) planned simultaneous therapeutic procedures during angiography (to prevent confusion regarding the source of adverse events from simultaneous therapeutic procedures), (3) women who were pregnant, (4) history of iodine based contrast allergy, and (5) active systemic infection or organ dysfunction (ie, severe cardiac, hepatic, or renal insufficiency).

After obtaining informed consent, physicians identified the target vessels for selective catheterization based on the purpose of cerebral angiography and entered the target vessels into the EDC system. The target vessels included the common carotid artery (CCA), ICA, external carotid artery (ECA), subclavian artery (SCA), VA, and their branch vessels. After the target vessels were entered into the EDC system, patients were randomly allocated in a 1:1 ratio by network randomization to either the experimental group, where robotic procedures were performed, or to the control group, where manual procedures were carried out.

### Procedure

The femoral artery was manually accessed using the Seldinger technique in both the robotic assisted and manual groups. The 5 F angiography catheter was connected to the Y valve, accompanied by a sustaining high pressure water injection system. Subsequently, a 0.035 inch guide wire was inserted into the Y valve. Preoperative catheter and guide wire assembly procedures did not differ between the two groups. The difference was that for the robotic assisted group, the entire body of the robot was covered with three sterile transparent drapes, and three robotic cassettes were assembled. Then, the catheter, Y valve, and guidewire were loaded into the three corresponding robotic cassettes. The angiographic catheter was manually inserted into the sheath.

During the procedure, in the robotic assisted group, the neurointerventional physicians, seated behind a radiation shielded workstation or in the console room, controlled the fluoroscopy and operated the robot by foot treadle and two control sticks, mirroring the relative positions of the guidewires and catheters on the procedural table. The unique control sticks align with interventionalists' muscle memory for catheter/guidewire manipulation, reducing cognitive load. The movements of the catheter and guidewire manipulator on the robot side were synchronized in real time with the movements of the control sticks, ensuring seamless and accurate operation. The doctor received continuous video feedback and communicated with the bedside assistant using a microphone. During the course of the procedure, in accordance with the physician's professional judgment, manual operation could be resorted to in the event of an emergency situation arising or if the robot was incapable of reaching the target vessels. For the patients in the control group, the physician completed the entire angiography process manually following the traditional approach. In both groups, catheter exchanges for anatomical reasons during the procedure were permitted. However, any conversion from robotic to manual operation was recorded and considered a technical failure.

This study was a pre-marketing clinical trial for registration, conducted under the strict supervision of China's National Medical Products Administration (NMPA). Therefore, the entire study process was overseen by a third party clinical research organization for data collection and a clinical research associate for monitoring adverse events, including a conversion from robotic to manual operation, during the procedures. The NMPA conducted multiple unannounced inspections at each participating center to ensure data reliability and patient rights.

### Outcomes and definitions

The primary outcome was clinical success, defined as the successful completion of cerebral angiography by the neurointerventional doctor using the test robotic system or manual cerebral angiography. Secondary outcomes were technical success, overall surgery time, pre-puncture setup time, puncture-to-unsheathed time, mean catheterization time per target vessel, X-ray fluoroscopy time, and primary operator's radiation dose. Technical success rate was defined as the proportion of pre-identified target vessels that were successfully catheterized through a dual verification mechanism: (1) intraoperative supervision: any conversion to manual operation or robotic system malfunctions were documented and classified as technical failures; and (2) an independent core laboratory validation: the core laboratory systematically compared angiography images with the pre-identified target vessel list.

To reflect the patient's feelings in the real world, overall surgery time refers to the period from the patient on the table to procedure completion, including (1) pre-puncture set-up time: patient positioning, robotic system assembly (in robotic group), and device preparation, and (2) puncture-to-unsheathed time. X-ray fluoroscopy time was recorded by the DSA machine, directly reflecting patients' radiation dose. The primary operator's radiation dose was measured by a pocket sized radiation dosimeter on the primary operator. The safety endpoints were the incidence of perioperative vascular injuries (including but not limited to perforation, dissection, and pseudoaneurysm), any adverse events (AEs), serious adverse events (SAEs), and device malfunctions.

### Sample size and statistical analyses

The primary hypothesis was that the clinical success rate in the robotic group would be non-inferior to that in the control group. Based on clinical experience and relevant literature, manual angiography is assumed to have a success rate of 96%.[10–12] At the outset of our study, there were no published RCTs on interventional robots. Given the limited existing data, a multidisciplinary panel (including interventional neurologists, statisticians, and regulatory experts) discussed relevant non-inferiority margin according to China's NMPA guidelines. A clinically relevant non-inferiority margin of 12% was chosen as the acceptable difference between groups simultaneously,[10 13 14] with a one sided significance level alpha of 2.5% and an estimated 5% withdrawal or loss to follow-up rate. Under these conditions, randomizing a total of 130 patients would provide 80% power to demonstrate non-inferiority.

Statistical analyses were conducted with SAS 9.4. For continuous variables, descriptive statistics included mean, SD, median, minimum, maximum, lower quartile (Q1), and upper quartile (Q3). For categorical variables, descriptive statistics included frequency, incidence rate, and composition ratio of each category. The non-inferiority test was based on an asymptotic Z test. Normally distributed continuous variables were compared using the Student's t test. Categorical variables were compared with a $\chi^2$ test or Fisher's exact test. All statistical tests used a two sided approach, and a P value $<0.05$ was considered to be statistically significant.

## RESULTS

### Baseline characteristics

Between March and June 2023, 145 patients were screened and 130 met the inclusion and exclusion criteria and provided written informed consent. Before randomization, 458 vessels were identified as the target vessels, with an average of 3.52 target vessels per patient, based on the patient's medical history. After randomization, 64 patients with 217 target vessels were assigned to the experimental group and 66 patients with 241 target vessels were assigned to the control group. Two participants withdrew from the study: one patient in the experimental group did not undergo DSA because of a sudden onset of atrial fibrillation and was instead transitioned to CT angiography and another patient in the control group withdrew consent for DSA due to a recurrence of an inguinal hernia. No patients crossed over or were lost to follow-up. Therefore, 128 patients were included in both the full analysis set and the per protocol set (figure 2). Demographic characteristics, indications or reasons for angiography, and target vessels are presented in table 1.

The median age of patients was 59.6±11.36 years in the experimental group and 61.3±10.99 years in the control group. In the experimental group, the target vessels included 86 (39.63%) CCAs, 29 (13.36%) ICAs, 6 (2.76%) ECAs, 74 (34.10%) SCAs, 18 (8.29%) VAs, 3 (1.38%) superficial temporal arteries, and 1 (0.46%) occipital artery. In the control group, the target vessels were 81 (33.61%) CCAs, 36 (14.94%) ICAs, 9 (3.73%) ECAs, 83 (34.44%) SCAs, 23 (9.54%) VAs, 4 (1.66%) superficial temporal arteries, 4 (1.66%) occipital arteries, and 1 (0.41%) ascending cervical artery. There was no significant difference in the distribution of target vessels between the two groups.

### Clinical success rates and technical success rate

The endpoint results are shown in table 2. Based on the intraoperative supervision and core laboratory validation, the clinical success rates reached 100% in both the experimental and

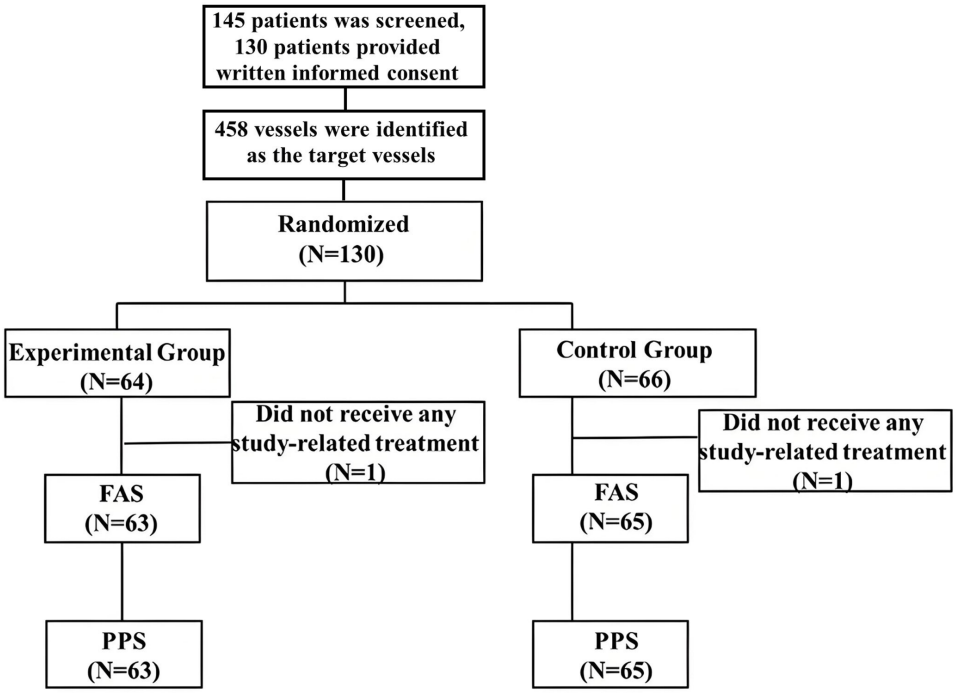


**Figure 2** Randomization and treatment of patients. FAS, full analysis set, PPS, per protocol set.

control groups. The 95% CI for the difference in success rates between the two groups was −5.75% to 5.58%). Notably, the lower limit of −5.75% exceeded the non-inferiority margin of −10%, thereby validating the non-inferiority conclusion. These results suggest that the trial device can effectively complete cerebral angiography examinations. All selective intubation procedures and imaging for all patients were successful, resulting in 100% technical success, with no difference observed between the two groups.

**Table 1** Demographic characteristics

| Characteristics | Experimental group (n=63) | Control group (n=65) | P value |
|---|---|---|---|
| Age (years) (mean (SD)) | 59.6 (11.36) | 61.3 (10.99) | 0.416 |
| Sex (male) | 32 (50.79) | 36 (55.38) | 0.603 |
| Height (cm) (mean (SD)) | 162.9 (8.06) | 162.4 (7.55) | 0.817 |
| Weight (kg) (mean (SD)) | 64.3 (12.52) | 64.5 (10.21) | 0.893 |
| Indications for angiography | | | |
| Aneurysm or follow-up after aneurysm embolization | 30 (47.62) | 32 (49.23) | 0.954 |
| Artery stenosis or follow-up after angioplasty | 24 (38.10) | 23 (35.39) | |
| Follow-up for DAVF, AVM, or MMD | 9 (14.29) | 10 (15.38) | |
| Target vessels | 217 | 241 | |
| Common carotid artery | 86 (39.63) | 81 (33.61) | 0.669 |
| Internal carotid artery | 29 (13.36) | 36 (14.94) | |
| External carotid artery | 6 (2.76) | 9 (3.73) | |
| Subclavian artery | 74 (34.10) | 83 (34.44) | |
| Vertebral artery | 18 (8.29) | 23 (9.54) | |
| Other | 4 (1.84) | 9 (3.73) | |

Values are number (%) unless indicated otherwise.
AVM, arteriovenous malformation; DAVF, dural arteriovenous fistula; MMD, moyamoya disease.

## Other secondary endpoints

The catheterization time per target vessel was 9.05±6.52 min in the experimental group and 8.03±5.26 min in the control group, with no significant difference (P=0.882) between the groups. The X-ray fluoroscopy times in the experimental group and control group were 12.41±10.31 min and 10.70±6.34 min,

**Table 2** Endpoint results

| Endpoints | Experimental group (n=63) | Control group (n=65) | P value |
|---|---|---|---|
| Clinical success (n (%)) | 63 (100) | 63 (100) | NA |
| Technical success (n (%)) | 63 (100) | 63 (100) | NA |
| Overall surgery time (min) (mean (SD)) | 64.19 (20.06) | 52.49 (16.83) | <0.001 |
| Pre-puncture set-up time (min) (mean (SD)) | 34.59 (10.43) | 24.44 (13.97) | <0.001 |
| Puncture-to-unsheathed time (min) (mean (SD)) | 29.60 (16.57) | 28.05 (13.31) | 0.882 |
| Mean catheterization time per target vessel (min) (mean (SD)) | 9.05 (6.52) | 8.03 (5.26) | 0.247 |
| Primary operator's radiation dose (μSv) (mean (SD)) | 1.67 (3.49) | 43.63 (38.95) | **< 0.001** |
| X-ray fluoroscopy time (min) (mean (SD)) | 12.41 (10.31) | 10.70 (6.34) | 0.701 |
| Dose of contrast medium (mL) (mean (SD)) | 53.89 (18.64) | 57.78 (20.05) | 0.257 |
| Types of angiographic catheters (n) | | | |
| Single curve catheter | 61 | 65 | 0.486 |
| MPA1 catheter | 8 | 4 | |
| Simo catheter | 5 | 3 | |
| Perioperative vascular injuries | 0 (0) | 0 (0) | NA |
| Adverse events (n (%)) | 13 (20.63) | 10 (15.38) | 0.495 |
| Serious adverse events (n (%)) | 1 (1.59%) | 2 (3.08%) | 1.000 |

respectively (P=0.701). This indicates that robotic assisted angiography did not increase X-ray radiation dose received by patients. The primary operator's radiation dose was significantly lower in the experimental group (P<0.001), with 1.67±3.49 $\mu$Sv in the experimental group and 43.63±38.95 $\mu$Sv in the control group. The dose of contrast medium was 53.89±18.64 in the experimental group and 57.78±20.05 in the control group (P=0.257). These findings indicate that the robotic system can protect doctors from radiation damage without increasing radiation exposure to patients, thus avoiding the situation where doctors are protected but patients' interests are compromised.

As shown in table 2, the types of catheters used included single curve catheters, Simo angiographic catheters, and MPA1 angiographic catheters. Catheter exchanges occurred in both groups. In the experimental group, 11 catheter exchanges were performed, none of which led to a conversion from robotic to manual operation. In the control group, seven catheter exchanges were performed. There was no significant difference in the types of catheters used between the two groups. The overall surgery time was 64.19±20.06 min in the experimental group and 52.49±16.83 min in the control group. The pre-puncture set-up time was longer in the robotic group (34.59±10.43 vs 24.45±13.97, p<0.001), while the puncture-to-unsheathed time showed no difference (P=0.247). These findings suggested that the preoperative installation of the robotic instruments required more time.

### Safety endpoints

In this trial, we observed no perioperative vascular injuries or device malfunctions was observed, both registering at 0%. A total of 23 patients encountered 35 AEs. Of these, three patients experienced four SAEs. In the experimental group, 13 patients reported AEs, giving an incidence rate of 20.63% (13/63). In the control group, 10 patients experienced AEs, corresponding to an incidence rate of 15.38% (10/65). There was no statistically significant difference between the two groups in terms of AE incidence.

With respect to SAEs, in the experimental group, one patient had contrast induced encephalopathy, with symptoms including blurred vision, headache, vomiting, and high blood pressure. Fortunately, these symptoms subsided within 24 hours after administration of appropriate medication. In the control group, one patient developed herpes zoster accompanied by a pulmonary infection on the day after surgery, leading to a prolonged hospital stay. Also, another patient in the control group manifested symptoms of contrast allergy after surgery, and the symptoms were alleviated following treatment.

## DISCUSSION

Our randomized controlled trial demonstrated that the PANVIS-A robotic system achieved the same rates of clinical success and technical success in cerebral angiography procedures as those of manual operation, without increasing the X-ray radiation dose received by patients. Moreover, the primary operator's radiation dose was significantly reduced with the use of the robotic system. Physicians can be freed from the radiation intensive working environment, thereby mitigating the occupational hazards associated with radiation exposure. From the patient experience perspective, the puncture-to-unsheathed time was similar between the two groups. However, the pre-puncture set-up time was longer in the robotic group. This finding suggests that robots have not compromised patients' surgical experiences. However, further optimization is necessary to streamline the preoperative preparation process for robotic procedures. Regarding safety endpoints, no robot related adverse event or device malfunction was observed.

Robots are increasingly recognized as an indispensable tool in a variety of medical procedures. Especially in the field of interventional surgery, the application of robots holds great promise and necessity, as it may prevent occupational injuries to doctors caused by radiation and heavy protective suits. Since 2012, the CorPath robotic platform (Corindus, a Siemens Healthineers Company, Waltham, Massachusetts, USA) has been used in percutaneous coronary intervention.[15] Insights gleaned from applications under these indications reveal that the primary advantages of robotic assistance encompass augmented procedural and technical exactitude, along with a reduction in the radiation dose during fluoroscopic procedures. However, when applied to neurointervention, the robots designed for cardiovascular intervention still face many technical challenges. For example, Weinberg *et al* compared robotic assisted carotid stenting with manual carotid stenting and found that the robot could only navigate the catheter to the target vessel from the aortic arch.[16] This limitation was due to the short range of catheter motion delivered by the CorPath robotic platform. From the perspective of technical details of the CorPath, the catheter and its Y valve are fully fixed to the robotic body, which moves en bloc along a sliding rail on the robotic arm to advance or retract the catheter through the introducer sheath. However, the sliding rail has a limited range (±10 cm), resulting in a total working distance of 20 cm. This design cannot accommodate the ≥70 cm travel distance (from the femoral sheath to cerebral vessels) required for cerebral angiography. Consequently, robotic assisted neurointervention necessitates a robot specifically engineered to accommodate the unique features of neural interventions.

Therefore, Shenzhen Institute of Advanced Biomedical Robot developed a novel robotic system for diagnostic cerebral angiography, addressing neurointervention specific challenges through biomimetic mechanisms and ergonomic optimization. The robot was designed in a master–slave mode, with a master controller located outside the operating room and a slave manipulator within. The PANVIS-A uses a clamping device mechanism that mimics the manual pinch and push and twisting motion of a physician's thumb and index finger, capable of delivering the guidewire and catheter over the entire distance. These delivery devices also enable complex movements of the guidewire and catheter, such as rotational delivery of the guidewire or catheter, and simultaneous delivery of the guidewire and catheter (figure 1A, B).

Also, the most notable innovation of the PANVIS-A robot is the catheter on finger control sticks. The novel control sticks are positioned horizontally, simulating the relative positions of guidewires and catheters on the operating table. By mimicking these intuitive movements, the PANVIS-A system may reduce the learning curve and allow experienced interventionalists to leverage their existing skills seamlessly. The robot offers two modes of delivery: continuous delivery and stepping delivery. The stepping delivery mode can achieve a one-to-one reproduction of the doctor's movements on the control sticks to the delivery devices with sub-millimeter precision (figure 1C, D).

To our knowledge, only six studies have reported the use of robotic systems for diagnostic cerebral angiography.[4 10 17–20] Most of these studies provided level 4 evidence, indicating a limited body of high quality research in this field. Currently, only one RCT has demonstrated that robotically performed diagnostic cerebral angiography is non-inferior to manual procedures.[10] The transfemoral approach is currently the most commonly used access route for cerebral angiography. In China, the success rate of

completing cerebral angiography via the transfemoral approach ranges from 95.1% to 99%.[10–12] The VIR-2 was the first experimental vascular interventional robot for cerebral angiography, reported in 2016.[18] However, the details of the mechanics were not described. Fifteen patients underwent successful cerebral angiography without complications. But no subsequent study of this robot has been reported. There was one study about the Magellan robotic system performing cerebral angiography,[20] but only nine patients were reported, without clearly defined patient selection criteria or evaluation of endpoints. Beaman *et al* reported 113 patients undergoing cerebral angiography with the CorPath in a 2 year multicenter study.[4] Only 88 were successfully completed (77.9%), with failures attributed to difficult patient anatomy, limited working length of the catheter, cassette failure, robotic arm failure, and console failure.

Liu *et al* conducted an RCT to evaluate the safety and efficacy of the YDHB-NS01 Robot (Yidu Hebei Robot Technology, Beijing, China) in cerebral angiography.[10] A total of 257 patients completed this trial. The rate of the catheter reaching the target vessel was 99.23% and 100.00% in the control and experimental groups, respectively. No statistically significant differences were found in the radiation doses of patients, mean operation time, or adverse effects. Thus angiography using the assistance of a robotic system was not inferior to traditional angiography. However, this study did not analyze the radiation doses of physicians.

The PANVIS-A robotic system represents an advancement on previous robots. To better adapt to the real world, our study did not set specific inclusion or exclusion criteria for aortic arch types. In the study, three types of catheters, including single curve, MPA1, and Simo, were used in the experimental group, which confirmed the system's compatibility. Despite the occurrence of catheter exchanges, the robotic system maintained its performance without extending procedural time. This suggests that the robotic system can handle catheter exchanges without significant impact on procedural efficiency. In addition, critical endpoints, including clinical success and technical success, were adjudicated by an independent core laboratory based on the records of process. Our trial is the first study to show that the robotic system is safe and effective for assisting cerebral angiography, notably reducing primary operators' radiation exposure. In line with the recent RCT, our findings underscore the great prospect of robotic systems in the field of neurointervention. However, we found that establishing the sterile field (using three pre-sterilized instrument cassettes and two disposable transparent plastic drapes) is the most time consuming step. While cassette assembly is efficient (installed in <1 min), draping requires sequential alignment and fixation of each cover over the robotic arms and body. We have prototyped a unified sterile barrier that combines all covers into a single prefolded disposable bag.

Our study also had several limitations. We acknowledge that potential selection bias, relatively wide non-inferiority margin, and underpowered sample size are limitations, which may be unable to detect rare but critical complications. To prevent confusion regarding the source of AEs from simultaneous therapeutic procedures (such as aneurysm embolization or carotid artery stenting), patients with planned simultaneous therapeutic procedures during angiography were excluded from this study. This may lead to a low proportion of vertebral artery catheterizations. The preoperative installation of the robotic instruments needs further optimization, especially in sterile preparation. The existing robot systems only support the control of one guidewire and one catheter. In the future, it will be necessary to achieve the control of more than three catheters and one guidewire through the improvement of the delivery system to perform the complex coaxial technology. In addition, it is also important to be able to control the guidewire and catheter in parallel to perform the rapid exchange technology. Such technological improvement can be adapted to most neurointerventional surgical procedures, including stent assisted aneurysm embolization, mechanical thrombectomy, and carotid artery stenting, for example. Although our study had limitations, further research and development are necessary to fully realize its clinical potential and optimize patient outcomes.

## CONCLUSIONS

This trial demonstrated that the robotic system was safe and effective for assisting cerebral angiography, with a notable reduction in primary operators' radiation exposure. However, the preparation process of the robot still requires further optimization.

**Contributors** Conception, design, and drafting the manuscript: Yongxin Z and HXu. Acquisition of the data and reviewing/editing the manuscript: Yongxin Z, HX, JS, W-HC, Yongwei Z, MC, TY, Y-MW, GC, JG, PY, SG, and JL. Supervision, analysis, and interpretation of the data: PY and JL. Design of the robot: JG and SG. Yongxin Z is the guarantor.

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**Competing interests** None declared.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was approved by Shanghai Changhai Hospital Ethics Committee (CHEC2022-233). Participants gave informed consent to participate in the study before taking part.

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**Data availability statement** Data are available upon reasonable request.



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## REFERENCES

1 Łajczak PM, Jóźwik K, Nowakowski P, *et al*. Machine Meets Brain: A Systematic Review of Effectiveness of Robotically Performed Cerebral Angiography Interventions. *World Neurosurg* 2024;186:235–41.
2 Dokollari A, Sicouri S, Erten O, *et al*. Long-term clinical outcomes of robotic-assisted surgical coronary artery revascularisation. *EuroIntervention* 2024;20:45–55.
3 Weisz G, Metzger DC, Caputo RP, *et al*. Safety and feasibility of robotic percutaneous coronary intervention: PRECISE (Percutaneous Robotically-Enhanced Coronary Intervention) Study. *J Am Coll Cardiol* 2013;61:1596–600.
4 Beaman C, Gautam A, Peterson C, *et al*. Robotic Diagnostic Cerebral Angiography: A Multicenter Experience of 113 Patients. *J NeuroIntervent Surg* 2024;16:726–30.
5 Guo J, Guo S, Yu Y. Design and characteristics evaluation of a novel teleoperated robotic catheterization system with force feedback for vascular interventional surgery. *Biomed Microdevices* 2016;18:16–76.
6 Yang C, Guo S, Bao X. An Isomorphic Interactive Device for the Interventional Surgical Robot in Vivo Study. *Micromachines (Basel)* 2022;13:111.
7 Yang C, Guo S, Bao X, *et al*. A vascular interventional surgical robot based on surgeon's operating skills. *Med Biol Eng Comput* 2019;57:1999–2010.
8 Zhang C, Guo S, Xiao N, *et al*. Transverse microvibrations-based guide wires drag reduction evaluation for endovascular interventional application. *Biomed Microdevices* 2018;20:12–69.
9 Chinese Society of Neurology, Chinese Medical Association. Neurovascular Intervention Collaborative Group of Chinese Society of Neurology, Chinese Medical Association. Chinese Expert Consensus on the Operating Standards of Cerebral Angiography. Chinese Journal of Neurology 2018;51:7–13.

10 Liu H, Li C, Ren S, *et al*. Efficacy and safety of a neurointerventional operation robotic assistance system in cerebral angiography. *Stroke Vasc Neurol* 2024;9:243–51.
11 Chen W, Song XF, Wan M, *et al*. The Effects of Diagnosis-Related Group Payment on Diagnostic Cerebral Angiograms through a Transradial and Transfemoral Approach: A Comparative Observational Study. *J Healthc Eng* 2022;2022:9670757.
12 Batista S, Oliveira L de B, Diniz JBC, *et al*. Transradial versus transfemoral approach in cerebral angiography: A meta-analysis. *Interv Neuroradiol* 2023;2023:15910199231212520.
13 Zhou T, Li T, Zhu L, *et al*. Comparing the efficacy and safety of the Skyflow device with those of the Solitaire FR stent in patients with acute ischemic stroke: a prospective, multicenter, randomized, non-inferiority clinical trial. *J Neurointerv Surg* 2022;14:1130–4.
14 Luo G, Yan X, Xiao G, *et al*. Comparing a novel Catfish flow restoration device and the Solitaire stent retriever for thrombectomy revascularisation in emergent largevessel occlusion stroke: a prospective randomised controlled study. *Stroke Vasc Neurol* 2023;8:435–43.
15 Maor E, Eleid MF, Gulati R, *et al*. Current and Future Use of Robotic Devices to Perform Percutaneous Coronary Interventions: A Review. *J Am Heart Assoc* 2017;6:e006239.
16 Weinberg J, Sweid A, Sajja K. Comparison of Robotic Assisted Carotid Stenting and Manual Carotid Stenting Through the Transradial Approach. *Neurosurgery* 2020;67.
17 Jiang Y, Liu K, Li Y. Initial Clinical Trial of Robot of Endovascular Treatment with Force Feedback and Cooperating of Catheter and Guidewire. *Appl Bionics Biomech* 2018;2018:9735979.
18 Lu W, Xu W, Pan F, *et al*. Clinical application of a vascular interventional robot in cerebral angiography. *Int J Med Robot* 2016;12:132–6.
19 Sajja KC, Sweid A, Al Saiegh F, *et al*. Endovascular robotic: feasibility and proof of principle for diagnostic cerebral angiography and carotid artery stenting. *J Neurointerv Surg* 2020;12:345–9.
20 Vuong SM, Carroll CP, Tackla RD, *et al*. Application of emerging technologies to improve access to ischemic stroke care. *Neurosurg Focus* 2017;42:E8.