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Efficacy and safety of a neurointerventional operation robotic assistance system in cerebral angiography

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ABSTRACT

Background At present, neurointerventional surgery requires angiographers to perform operations in the digital subtraction angiography (DSA) room. Ionising radiation and chronic joint damage are still unavoidable for angiographers. Therefore, we researched and developed a neurointerventional robot-assisted system, which is operated by angiographers in an operating room outside the DSA room. We have conducted a prospective, multicentre, randomised controlled trial to evaluate the safety and efficacy of a robot-assisted system in human cerebral angiography. In the future, this research will provide a platform for the research and development of an intelligent surgical system and bring revolutionary progress in neurointerventional surgery.

Methods From December 2020 to December 2021, 260 patients were enrolled from three medical centres, who were randomly and equally divided into a robot-assisted system group and a clinical routine cerebral angiography group. The success rate of angiography, the rate of the catheter reaching the target vessel, the operation time, X-ray radiation exposure and the incidence of related adverse events were compared between the two groups.

Results A total of 257 patients completed this trial; baseline characteristics of the two groups did not differ significantly. The success rate of angiography in both the control group and the experimental group was 100%. The rate of the catheter reaching the target vessel was 99.23% and 100.00% in the control and experimental groups, respectively. For the control versus experimental groups, the angiographic operation time was 48.59±25.60 min versus 47.94±27.49 min, respectively; the X-ray radiation dose was 735.01±554.77 mGy versus 821.65±705.45 mGy, respectively; and the incidence of adverse events was 23.44% versus 22.48%, respectively. No statistical differences were present between the two groups.

Conclusion The robot-assisted surgical system is more convenient for cerebral angiography and is as safe and effective as the traditional cerebral angiography.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ At present, neurointerventional surgery requires angiographers to perform operations in the digital subtraction angiography (DSA) room. Ionising radiation and chronic joint damage are still unavoidable for angiographers. Therefore, we researched and developed a neurointerventional robot-assisted system, which is operated by angiographers in an operating room outside the DSA room.

WHAT THIS STUDY ADDS

⇒ We have conducted a prospective, multicentre, randomised controlled trial to evaluate the safety and efficacy of a robot-assisted system in human cerebral angiography. As far as we know, it is the largest clinical study of a vascular surgery assistance system involving clinical samples.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ It provides clinical experience and data for the R&D, transformation and marketing of subsequent neurointerventional therapy products and also provides a basis for the government to formulate policies for introducing relevant medical products into clinical application. In the future, this research will provide a platform for the research and development of an intelligent surgical system and bring revolutionary progress in neurointerventional surgery.

INTRODUCTION

The term 'robot' is derived from the Czech word 'robota' used in a Czech play in 1920 to mean servitude or forced labour.[1] Robots were first used in clinical practice in 1985.[2 3] To date, it has been used in a variety of surgical fields.[4–6] In the field of surgical treatment of cerebrovascular diseases, the emergence of vascular interventional technologies has changed the way of disease treatment. Nowadays, neurointerventional therapy is widely applied, which plays an increasingly important role in the treatment of haemorrhagic diseases such as aneurysms and vascular malformations and ischaemic diseases such as acute ischaemic stroke. However, with the rapid development of neurointerventional therapy, many concurrent problems gradually appeared, for example, ionising radiation. Although angiographers wear appropriate personal protective equipment, potential exposure still cannot be completely avoided, and wearing personal protective equipment and standing for a long time may cause chronic

damage to the doctors' joints and ligaments.[7] Thus, with the help of the robot-assisted system, the angiographers will not be exposed to ionising radiation in the operating room outside the digital subtraction angiography (DSA) room. They generally take a sitting position and have no need to wear personal protective equipment, so chronic damage to joints and ligaments can be avoided. Because standardised interventional manoeuvres consist of a set of forward and backward linear motion combined with rotational manoeuvres, this type of repetitive motion is exactly what the robot does best. We research and developed this interventional unit, a neurointerventional surgery assistance system, YDHB-NS01 (Yidu Hebei Robot Technology Co., Ltd., Hebei Province, China), which can provide a foundation for carrying more diversified and smarter devices in the near future. The platform can also offer possibilities for telemedicine for patients and can be used for training interventional doctors. This study is a clinical study related to transformational products. As far as we know, it is the largest clinical study of a vascular surgery assistance system involving clinical samples. This project has been strongly supported by the government for many years and has become a key research and development project of the Ministry of Science and Technology of China. At present, we only use this system to perform whole-brain angiography for clinical research. This paper reports the use of this system in a multicentre, prospective, randomised controlled clinical trial to validate its safety and efficacy in clinical application. This is because cerebral angiography covers basic operations of vascular intervention, and the experimental design is relatively simple, the risk of clinical application is low, and it is easy to commercialise such product. It provides clinical experience and data for the R&D, transformation and marketing of subsequent neurointerventional therapy products, and it also provides a basis for the government to formulate policies for introducing relevant medical products into clinical application.

METHODS AND MATERIALS

This study is a randomised, parallel, controlled, non-inferiority multicentre clinical trial. It was completed at three centres: Beijing Chaoyang Hospital affiliated to Capital Medical University, Shanxi Provincial People's Hospital and the First Hospital of Hebei Medical University. Clinical study protocols were reviewed and approved by individual institutional review boards, and patients provided written informed consent. Through screening and evaluation, subjects who met the inclusion/exclusion criteria of the research plan were randomly divided into experimental and control groups at a 1:1 ratio. The experimental group had the minimally invasive vascular interventional surgery using the robot-assisted system, while the control group received the traditional cerebral angiography. Both treatments were performed by doctors with extensive experience in neurointerventional surgery to objectively evaluate the safety and effectiveness of the neurointerventional robotic assistance system. For details, please refer to online supplemental file 1.

Inclusion and exclusion criteria

Patients participating in this clinical trial were required to meet all of the following criteria: (1) the patient is 18–75 years old; gender is not limited; (2) the patient has cerebrovascular disease and requires interventional angiography; (3) the subject agrees to voluntarily sign the consent form. Patients who met any of the following criteria were excluded: (1) patients with severe infectious diseases such as bacteraemia and toxaemia; (2) patients with severe coagulation disorders; (3) patients with severe heart, brain, lung or other disease; (4) patients with implanted cardiac pacemakers or defibrillators or any other electronic device or metal part (This interventional robot system belongs to Class III equipment. The electromagnetic generated by it may affect the operation of cardiac pacemaker.); (5) patients with a history of epilepsy; (6) patients with arrhythmias; (7) patients who had experienced acute myocardial infarction within the past 6 months; (8) pregnant or lactating women and those planning to become pregnant within 1 year; (9) patients who had participated in any clinical trials of drugs and/or medical devices within 3 months before enrolment and (10) any patient, who after evaluated by researchers, was considered to have any other factor making them unsuitable for inclusion. The detail of experiment flowchart is shown in figure 1.

Design method

Randomisation design

A stratified block randomisation method was adopted, and SAS V.9.4 statistical software was used to generate random codes according to a 1:1 ratio of the control group to the experimental group. Eligible subjects were then randomly assigned to group according to the time of enrolment.

Blind design

This trial was a randomised, parallel, active control trial with no blinding. The operating standards adopted by the experimental group and the control group were consistent: all participating researchers received product operation training, and each centre was operated by two or more experienced neurointerventional doctors with intermediate professional titles or above. Each centre completed the same number of subjects in the experimental and control groups.

Clinical evaluation

The success rate of the angiography was used as the primary endpoint. Procedural success was defined as catheter arrival at the intended site with no complications. The incidence of clinical complications, adverse events (AEs) and performance indicators within 3 days after angiography (or, at the time of discharge, if this was <3 days) was used as the safety evaluation index. Complications include: (1) puncture related: perivascular haematoma

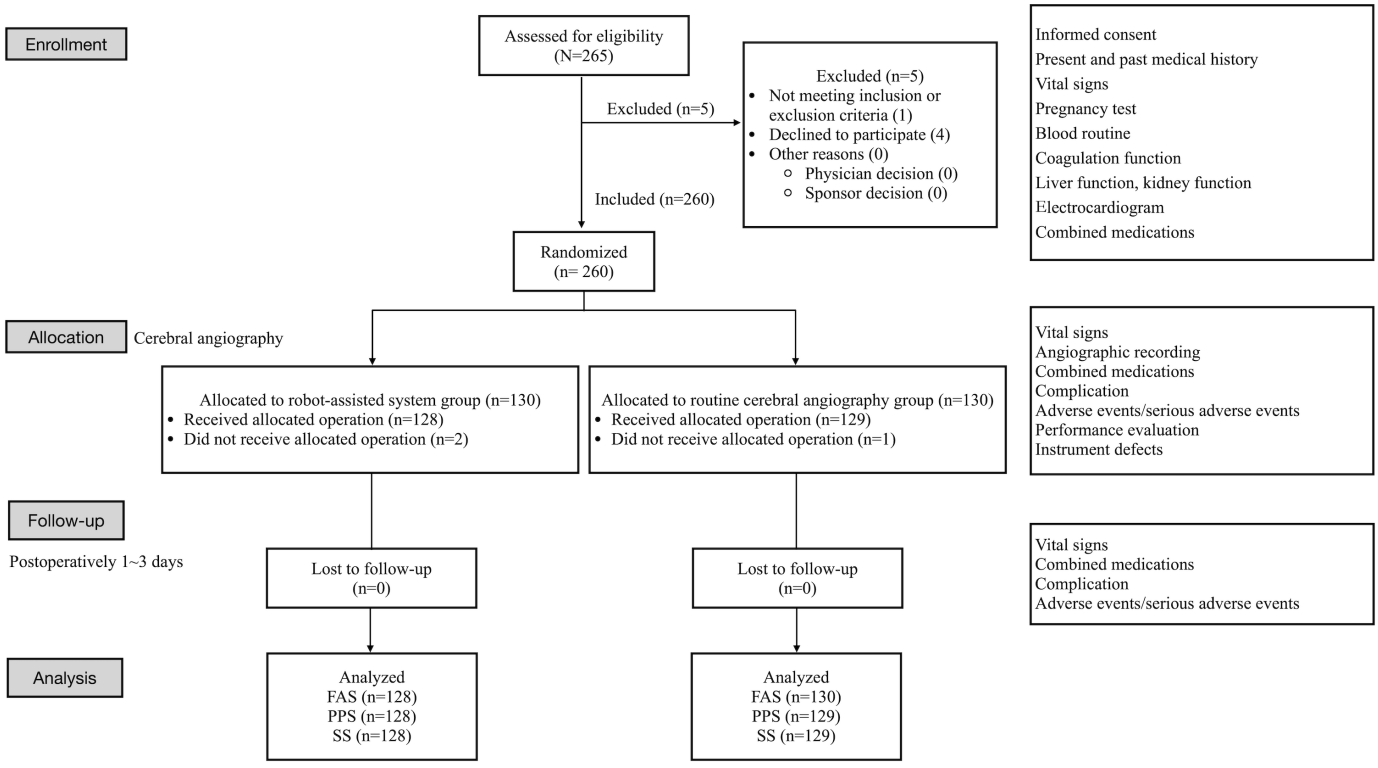

Figure 1 Experiment flowchart. FAS=number of people randomly enrolled–number of people who did not use any research equipment; PPS=FAS lost to follow-up or the patient withdraws from the study; SS=FAS–number without any safety assessment (lost to follow-up). FAS, full analysis set, PPS, per-protocol set, SS, safety analysis set.

puncture, vasospasm at the puncture site, vascular dissection, pseudoaneurysm, arteriovenous fistula, puncture site infection; (2) procedure related: intracranial vasospasm, atherosclerotic plaque sloughing, thrombosis, vascular injury, vascular dissection, vascular perforation, vascular rupture, vascular occlusion, pseudoaneurysm, arteriovenous fistula, haemorrhage, intracranial aneurysm or arteriovenous malformation, air embolism; (3) neurological complications: transient ischaemic attack, epilepsy, opisthotonistolus, complete amnesia, ischaemic stroke. AE include but are not limited to: metabolic and nutritional diseases, lung infections, increased blood pressure, elevated blood glucose, headache, constipation. The detail is in online supplemental table 1.

Operation time

As the assistance system cannot replace the doctor to puncture the femoral artery and place the arterial sheath, this procedure was done by the doctor in both groups. The so-called angiography time, thus, started from the time when the 5F angiography catheter entered the femoral artery and ended when the 5F angiography catheter was withdrawn from the femoral artery sheath after the end of the angiography.

Criteria for discontinuation of the trial/treatment

Subjects could withdraw from the trial for any of the following reasons. (1) Those who had allergic reactions or serious AEs and should stop the trial according to the doctor's judgement. (2) Those whose condition deteriorated during the trial and should stop the trial according to the doctor's judgement. (3) Those with poor compliance according to the investigator's judgement. (4) Subjects that withdrew voluntarily. (5) Subjects unwilling or unable to continue the clinical trial for any reason that asked the investigator to withdraw from the trial. (6) Subjects that did not explicitly request to withdraw from the trial, but no longer had follow-up.

Operation process

The experimental medical device was a minimally invasive vascular interventional surgery assistance system, model specification, YDHB-NS01. The patient was placed supine, the bilateral inguinal areas were disinfected, the right femoral artery was punctured and an 5F arterial sheath inserted. The 5F angiography catheter was connected to the Y valve and high-pressure water injection installed on the robotic arm and a 0.035" (0.89 mm) ultra-smooth guide wire inserted and fixed. The manipulator arm was fixed to the Y valve and the 5F angiography catheter sent into the arterial sheath. At this point, doctors in the experimental group left the operating room and entered the console room to perform selective angiography of the aortic arch and the superior arch artery. The single contrast dose and rated pressure of the high-pressure injector were identical to that used in the control group.

The doctor's console in the experimental group was used for remote control of the catheter controller, guide

wire controller output catheter and guide wire delivery actions. The doctor's console included steering handles for catheter and wire delivery control. During the operation, movements of the catheter and guide wire manipulator on the robot side are synchronised with the movements of the manipulation handle. When the handle corresponding to the catheter and the guide wire is pushed forward and backward, the catheter and the guide wire controller are likewise pushed forward and withdrawn at a fixed speed. When the handle is turned clockwise or counterclockwise, the catheter controller rotates the catheter correspondingly. The robotic body catheter and guidewire manipulator use linear advancement to drive the catheter and guidewire into or out of the blood vessel. The catheter manipulator is tightly connected with the catheter and does not undergo relative axial displacement during the operation. The guidewire manipulator adopts a repeating action, with the axial delivery operation of the guidewire performed in the manner of 'manipulator clamping—delivery; manipulator relaxation—gripper retraction' during the operation.

Sample size

The experimental group and the control group were randomly assigned in a ratio of 1:1. Taking the success rate of angiography as the main curative effect index, combined with the existing clinical evidence and the experience of clinical experts, the main curative effect was estimated to be 95%. Using a one-sided α=0.025, a power of 80% (1−β) and δ=8%, the PASS V.2020 software estimated the required sample size as 117 cases in each group. Considering a 10% dropout and exclusion, the sample size of the study was set to 130 cases in each group, for a total of 260 cases.

Statistical analysis

SAS V.9.4 software was used for statistical analysis. All statistical tests were one sided with α=0.05 (unless otherwise specified). P≤0.05 was considered a statistically significant difference (unless otherwise specified). All CIs are given as 95% CI. Quantitative indicators are described as number of calculated cases, mean, SD, median, minimum value (min), maximum value (max), P25 (Q1) and P75 (Q3). Classification indicators are described as the number of cases and percentages of each category. Comparison of the general conditions of the two groups was analysed using appropriate methods according to the type of indicator. Quantitative data were compared between groups using the two-sample t-test or the Wilcoxon rank sum test. Categorical data were analysed using the χ^2 test or the exact probability method. Ranked data were analysed by the Wilcoxon rank sum test or Cochran-Mantel-Haenszel test. Efficacy analyses were performed on a full analysis set (FAS) and on a per-protocol set (PPS) basis. All baseline demographic data analyses were performed based on the FAS, and safety assessments were performed on the Safety Analysis Set.

RESULTS

A total of 260 subjects were randomised into two groups, giving 130 cases in each of the experimental and control groups. In the experimental group, 128 cases were completed, while two cases (accounting for 1.53%) did not complete the trial. In the control group, 129 cases were completed, while one case (accounting for 0.77%) did not complete the trial.

Baseline

Summary statistics (mean±SD) for subjects in the experimental group were: age=53.83±9.97 years; height=165.93±7.73 cm; weight=70.99±10.61 kg; body mass index (BMI)=25.74 ± 3.12 kg/m^2. There were 48 male (37.50%) and 80 female subjects (62.50%); 124 (96.88%) subjects of Han nationality and four subjects (3.13%) of other ethnic groups. Summary statistics for the control group were: age=54.72±10.99 years; height=165.92±7.87 cm; weight=68.66±12.15 kg; BMI=24.85±3.38 kg/m^2. There were 59 male subjects (45.38%), 71 female subjects (54.62%) and 130 (100.00%) Han subjects. No statistically significant differences were present in demographic data between the two groups (p>0.05), indicating the basic demographic characteristics of the two groups were comparable (table 1).

The mean±SD of systolic blood pressure in the experimental and control groups was 129.83±15.49 mm Hg and 129.55±13.84 mm Hg, respectively; the mean±SD of diastolic blood pressure in the two groups were 80.62±9.90 mm Hg and 81.53±10.05 mm Hg, respectively. Respiration mean±SD was 18.30±0.99 times/min and 18.36±1.27 times/min in the experimental and control group, respectively. The mean±SD of body temperature was 36.42±0.24°C and 36.43±0.26°C in the experimental and control group, respectively. The mean±SD of heart rate was 74.40±7.80 beats/min and 74.86±9.31 beats/min in the two groups, respectively. No significant differences in vital signs occurred between the two groups before treatment (p>0.05).

In summary, the control and experimental groups were comparable, with no differences in demographic data, baseline characteristics or vital signs before treatment.

Main efficacy index: the success rate of angiography

FAS analysis results

The success rate of angiography in the experimental group was 100.00% and the success rate of angiography in the control group was 100.00%; there was no significant difference in the operation success rate between the two groups. The 95% CI of the difference in success rate of angiography between the two groups was (−0.03%, 0.03%), which was not statistically significant, and, thus the experimental group was non-inferior to the control group.

In the experimental group, the catheter reached the correct position in 128 cases (100.00%). In the control group, the catheter reached the correct position in 129 of 130 cases (99.23%). In the experimental group, 128

Table 1 Baseline demographics

Index	Experimental group	Control group	P value
Age, years			
Number of cases (number of missing)	128 (0)	130 (0)	0.4903
Mean±SD	53.82±9.97	54.72±10.99	
Sex, n (%)			
Number of cases (number of missing)	128 (0)	130 (0)	0.1987
Male	48 (37.50)	59 (45.38)	
Female	80 (62.50)	71 (54.62)	
Nationality, n (%)			
Number of cases (number of missing)	128 (0)	130 (0)	0.0592
Han nationality	124 (96.88)	130 (100.0)	
Others	4 (3.13)	0 (0.00)	
Height (cm)			
Number of cases (number of missing)	119(9)	122(8)	0.9883
Mean±SD	165.93±7.73	165.92±7.87	
Weight (Kg)			
Number of cases (number of missing)	119(9)	123(7)	0.1134
Mean±SD	70.99±10.61	68.66±12.15	
BMI (Kg/m^2)			
Number of cases (number of missing)	119(9)	122(8)	0.0362
Mean±SD	25.74±3.12	24.85±3.38	

BMI, body mass index.

cases (100.00%) were visualised by target angiography; in the control group, 129 cases (99.23%) were visualised by target angiography and 1 case (0.77%) was not visualised by target angiography. The 95% CI of the difference between the arrival position of the catheter and the angiographic imaging difference between the two groups was (−0.02% to 0.04%), which was not statistically significant, and it could be considered that the experimental group was non-inferior to the control group.

PPS analysis results

The control group sample size for PPS analysis was decreased due to one case dropping out when contact was lost.

The success rate of angiography in the experimental group was 100.00% and the success rate of angiography in the control group was 100.00%; success rate of the operation did not differ significantly between the two groups. The 95% CI of the difference in the success rate of angiography between the two groups was (−0.03%, 0.03%), which was not statistically significant, and it could be considered that the experimental group was non-inferior to the control group.

In the experimental group, the catheter reached position in 128 cases (100.00%); in the control group, the catheter reached position in 128 cases (99.22%) and in one case (0.78%) did not reach position. In the experimental group, 128 cases (100.00%) were visualised by target angiography; in the control group, 128 cases (99.22%) were visualised by target angiography and one case (0.78%) was not visualised by target angiography. The 95% CI of the difference between the arrival position of the catheter and the angiographic imaging difference between the two groups was (−0.02% to 0.04%), which was not statistically significant, and it could be considered that the experimental group was non-inferior to the control group.

The results of PPS and FAS were consistent, and, thus, we conclude that the experimental group was non-inferior to the control group (see tables 2 and 3 for details).

Secondary efficacy index: operation time

FAS analysis results

The mean and SD of angiography operation time in the experimental group was 47.94±27.49 min; the mean and SD of angiography operation time in the control group was 48.59±25.60 min. No significant difference in angiography operation time occurred between the two groups.

PPS analysis results

The mean and SD of angiography operation time in the experimental group was 47.94±27.49 min; the mean and SD of angiography operation time in the control group was 48.50±25.68 min. No significant difference in angiography operation time occurred between the two groups.

Table 2 The main evaluation index—angiographic success rate analysis results (FAS)

Index	Experimental group	Control group	Statistics	P value
Whether the angiography was successful				
Number of cases (number of missing)	128 (0)	130 (0)	NA	NA
Yes n (%)	128 (100.00)	130 (100.00)		
No n (%)	0 (0.00)	0 (0.00)		
	RD (test-control) and 95% CI 0.00 (–0.03 to 0.03)			
Whether the catheter was in place				
Number of cases (number of missing)	128 (0)	129 (1)	Fisher	1.0000
Yes n (%)	128 (100.00)	129 (99.23)		
No n (%)	0 (0.00)	1 (0.77)		
	RD (test - control) and 95% CI 0.01 (–0.02 to 0.04)			
Whether target vessel imaging was successful				
Number of cases (number of missing)	128 (0)	129 (1)	Fisher	1.0000
Yes n (%)	128 (100.00)	129 (99.23)		
No n (%)	0 (0.00)	1 (0.77)		
	RD (test–control) and 95% CI 0.01 (–0.02 to 0.04)			

FAS, full analysis set; RD, rate difference.

Thus, no difference in the angiography operation time occurred between the experimental group and the control group (see tables 4 and 5 for details).

The doses of radiation from X-rays (mGy)

The X-ray radiation dose received by subjects in the experimental group was 735.01±554.77 mGy and in the control group was 821.65±705.45 mGy. Radiation doses did not significantly differ between the two groups (see table 6 for details).

Safety indicators

Among the 129 subjects in the experimental group, 30 cases (43 events) had AEs, and the incidence of AEs was 23.44%; among the 129 subjects in the control group, 29 cases (47 events) had AEs, and the incidence of AEs was

Table 3 The main evaluation index—angiographic success rate analysis results (PPS)

Index	Experimental group	Control group	Statistics	P value
Whether the angiography was successful				
Number of cases (number of missing)	128 (0)	129 (0)	NA	NA
Yes n (%)	128 (100.00)	129 (100.00)		
No n (%)	0 (0.00)	0 (0.00)		
	RD (test–control) and 95% CI 0.00 (–0.03 to 0.03)			
Whether the catheter was in place				
Number of cases (number of missing)	128 (0)	129 (0)	Fisher	1.0000
Yes n (%)	128 (100.00)	128 (99.22)		
No n (%)	0 (0.00)	1 (0.78)		
	RD (test–control) and 95% CI 0.01 (0.02 to 0.04)			
Whether target vessel imaging was successful				
Number of cases (number of missing)	128 (0)	129 (0)	Fisher	1.0000
Yes n (%)	128 (100.00)	128 (99.22)		
No n (%)	0 (0.00)	1 (0.78)		
	RD (test–control) and 95% CI 0.01 (-0.02, 0.04)			

PPS, per-protocol set; RD, rate difference.

Table 4 Operating time analysis results (FAS)

Index	Experimental group	Control group	Statistics	P value
Operation time (min)				
Number of cases (number of missing)	128 (0)	130 (0)	t=0.20	0.8432
Mean±SD	47.94±27.49	48.59±25.60		
Median	45.00	45.00		
Q1, Q3	28.50, 60.50	30.00, 64.00		
Min, max	7.00, 173.00	5.00, 138.00		

FAS, full analysis set.

22.48% (the detail is in online supplemental table 1). These differences were not statistically significant. There were also no significant differences in body temperature, heart rate, respiration, systolic blood pressure and diastolic blood pressure between the experimental group and the control group during and following the operation (p>0.05). There were no related complications during the operation and postoperative follow-up in the experimental group and the control group.

DISCUSSION

The assistance system for vascular interventional surgery expands and extends the doctor's ability, in order to solve the problems and limitations of traditional vascular interventional surgery. The catheter manipulator robot body and the supporting mechanical arm are fixed on the operating bed and move synchronously with it. The catheter controller, the guide wire controller and the auxiliary support catheter are installed in the corresponding parts of the robot body. In addition, the catheter and the guide wire can independently move back and forth and rotate around the axis. The basic working mechanism of the robotic system is as follow: (1) the control device (e) is located outside the operating room; (2) the slave end operation device (a, b, c) is located on the operating room, and there is a catheter controller and guide wire controller (a), respectively, clamp and control the forward, backward and rotation of the catheter and guide wire; (3) by observing the DSA screen (d) located outside the operating room, the doctor can judge the position of the catheter and guide wire in real time, and control the forward, backward and rotation of the catheter and guide wire through the handle (e), so as to realise the surgical operation (figure 2 and online supplemental video).

In this trial, the operation success rate of both the experimental group and the control group was 100% and no intraoperative complications occurred. Thus, angiography using the assistance system is not inferior to traditional angiography in terms of safety. However, more complicated operations were not performed in this experiment. Preliminary clinical case reports have shown the feasibility of robotic-assisted systems in procedures such as stent-assisted embolisation of intracranial aneurysms and stenting of carotid atherosclerotic stenosis.[8] In theory, precision mechanical systems have a stability and accuracy surpassing that of human beings, but there is currently insufficient high-quality data to support the conclusion that the safety performance of robot-assisted systems is not inferior to traditional doctor operations in more complex surgical procedures. To adapt to more delicate and complex operations and obtain higher safety, feedback of force and instrument displacement changes should be incorporated into the robot handle in future. This will quantify the force given by the operator to the guide wire and catheter and enhance the degree of freedom the surgeon has during the operation. If the operating doctor exceeds an alert range, the system's warning will reduce risk during complex surgery.

Using the assistance system can reduce radiation exposure. To reduce the radiation exposure of patients and

Table 5 Operating time analysis results (PPS)

Index	Experimental group	Control group	Statistics	P value
Operation time (min)				
Number of cases (number of missing)	128 (0)	129 (0)	t=0.17	0.8646
Mean±SD	47.94±27.49	48.5±25.68		
Median	45.00	45.00		
Q1, Q3	28.50, 60.50	30.00, 64.00		
Min, max	7.00, 173.00	5.00, 138.00		

PPS, per-protocol set.

Table 6 The results of radiation dose analysis (SS) of the subject

Index	Experimental group	Control group	Statistics	P value
Subject's X-ray radiation dose (mGy)				
Number of cases (number of missing)	124 (4)	124 (5)	t=1.08	0.2834
Mean±SD	735.01±554.77	821.65±705.45		
Median	505.30	582.50		
Q1,Q3	417.50, 926.55	495.55, 965.71		
Min, max	233.63, 4940.56	216.50, 7138.93		

SS, safety analysis set.

especially operating physicians, many efforts have been made to reduce the amount of ionising radiation in DSA and protective equipment.[9] Reducing radiation exposure of patients relies on reducing exposure (surgery) time or use of other technical means to reduce radiation. It has been reported before that the use of neurointerventional assistance systems can reduce the radiation dose of the operator by nearly 95.2% or more and that the exposure of patients was also significantly reduced.[10] In the current clinical trial, the use of a robotic assistance system can avoid nearly 100% of radiation exposure for the operating doctor. However, due to the operation time (48.59±25.60 mins in the experimental group and 47.94±27.49 mins in the control group) and radiation exposure amounts (735.01±554.77 in the experimental group and 821.65±705.45 in the control group), there

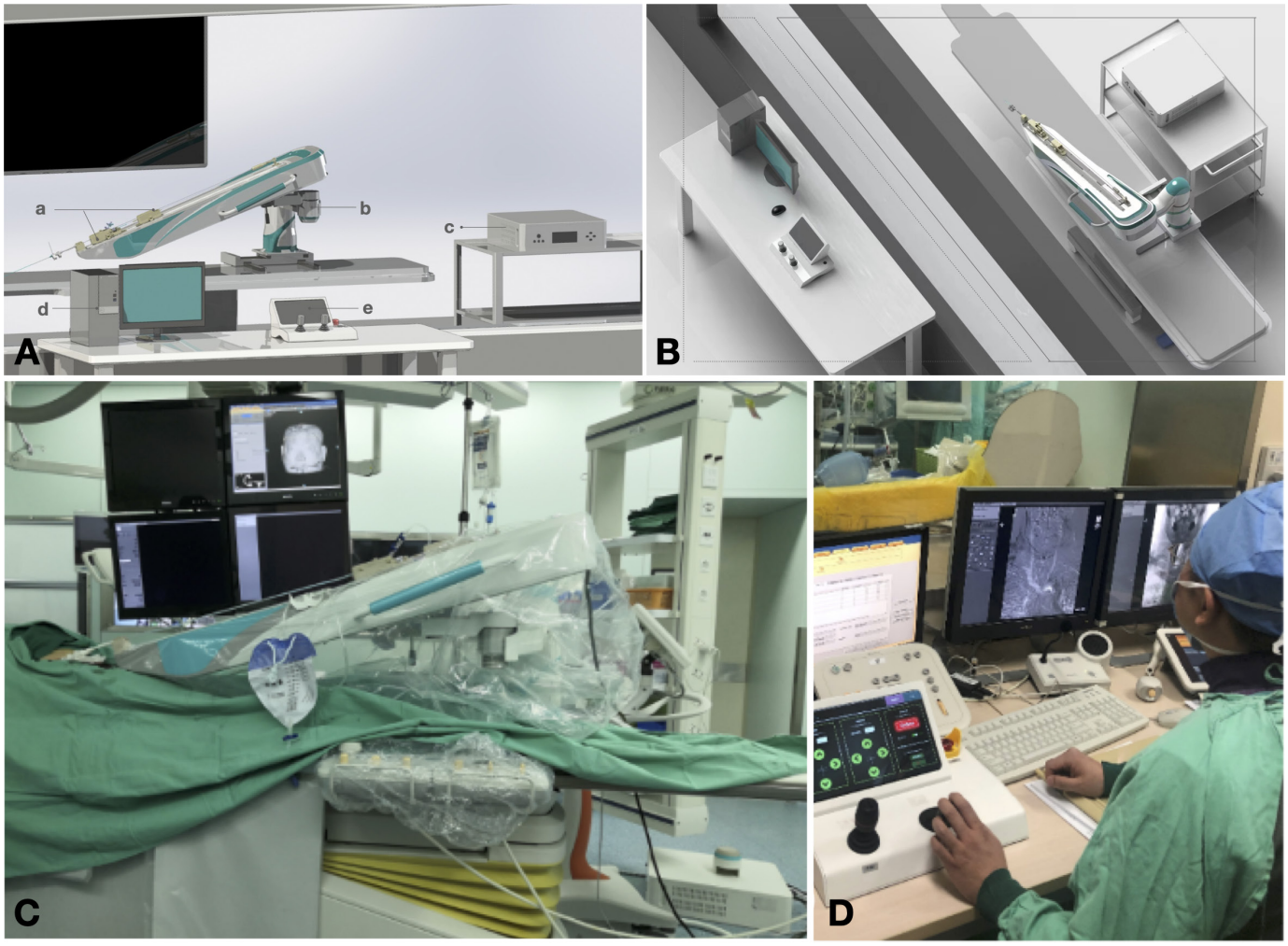

Figure 2 The basic structure of the robot assistant system. (A) a Disposable accessories, b Operating arm, c Control cabinet, d Workstation, e Operation console. (B) Inside the solid line: the operating room. Inside the dotted line: the control device room. (C) The robot working in the operating room. (D) The neurointerventionalist was controlling the robot outside of the operating room (in the control device room).

was no statistical difference and radiation exposure to patients was not reduced. If the doctor's proficiency in the operation of the system increases and the manoeuvrability of the assistance system improves, the radiation exposure time of the patient may be reduced.

In this study, in order to reduce the unknown risks of clinical trials and comply with ethical requirements, the doctor operating the assistance system has undergone thorough training and passed the assessment to be proficient in operating them. In addition, the joystick of the system is very flexible, allowing easy manipulation of the rotation and movement of the guidewire and catheter. The above may be the reason why there is no difference in operation time between the experimental group and the control group.

Another advantage of robots is their ability to be controlled remotely. Doctors can use this to perform remote surgical operations, making this a potential breakthrough technology for the treatment of acute stroke, especially the time-dependent mechanical thrombectomy. This could be carried out in primary hospitals, avoiding the delay past the best time for surgery caused by a need to transfer patients to another facility and especially benefiting patients in remote areas. However, this depends on the speed of data transmission across the network; the time delay must be negligible, or it will cause great danger for remote surgery. While other issues, such as equipment optimisation and strict supervision still need to be resolved, the potential of its realisation remains high.

CONCLUSION

The assistance system is easy to operate for cerebral angiography and has a success rate and operation time similar to the level of experienced doctors, indicating that it is safe and effective. At the same time, continuous improvement of the system, including additional force feedback, warning reminders to operators and multimodal image fusion, will enable more complex operations and more possibilities for the system.

Contributors HL designed data collection tools, monitored data collection for the whole trial, wrote the statistical analysis plan, cleaned and analysed the data, and drafted and revised the paper; CL implemented the trial in Department of neurosurgery, the 1st Affiliated Hospital, Hebei Medical University, analysed the data, and drafted and revised the paper; SR implemented the trial in Department of neurosurgery, the Shanxi Provincial People's Hospital, analysed the data, and drafted and revised the paper; TL monitored data collection for the whole trial, wrote the statistical analysis plan, and revised the draft paper; HZ, JJ, HY, YQ designed data collection tools, monitored data collection for the whole trial, analysed the data, and drafted and submitted the paper; JF monitored data collection for the whole trial, analysed the data, and revised the paper; YL and YW propose research directions, monitor and manage the progress of the whole research, designed data collection tools, monitored data collection for the whole trial, revised the paper and as the guarantor.

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Competing interests None declared.

Patient consent for publication Not applicable.

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