

ORIGINAL ARTICLE

Neurosurgery medical robot Remebot for the treatment of 17 patients with hypertensive intracerebral hemorrhage

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Abstract

Objective: To verify the minimally invasive surgical approach and therapeutic effects of using the medical neurosurgery robot Remebot to treat hypertensive intracerebral hemorrhage (HICH).

Methods: Clinical data for 17 HICH patients were analyzed retrospectively. Hematoma evacuation and tube drainage using Remebot frameless stereotaxic techniques were performed for all patients, and urokinase was injected into the hematomas after the operations.

Results: Robot-assisted stereotactic techniques can accurately guide hematoma punctures, and no deaths occurred among these patients. The average positioning error was 1.28 ± 0.49 mm. The average drainage duration was 3.4 days. The 3-month postoperative follow-up revealed improved neurological functions and quality of life for all patients.

Conclusions: The medical neurosurgery robot Remebot is minimally invasive, has high positional accuracy, and facilitates surgical planning according to the shape of the hematoma. Therefore, robot-assisted surgery using Remebot represents a safe and effective treatment method for hematoma evacuation and tube drainage in HICH patients.

KEYWORDS

drainage, frameless stereotaxy, hypertensive, intracranial hemorrhage, robotics

1 | INTRODUCTION

Hypertensive intracerebral hemorrhage (HICH) is an acute and dangerous cerebrovascular disease with very high mortality and very high morbidity. Therefore, early diagnosis and correct treatment can directly affect the survival and prognosis of patients.¹ Currently, no uniform standardized treatment method for HICH exists. Compared with traditional craniotomies, stereotactic puncture and drainage have the advantages of being minimally invasive and having high accuracy, which can significantly reduce surgical trauma, improve long-term quality of life, and improve nerve injury symptoms caused by long-term hematoma compression during conservative treatments. $^{2} \ensuremath{$

In August 2015, a clinical trial to investigate the clinical efficacy and safety of the domestic neurosurgical robot navigation and positioning system Remebot (Figure 1) was approved by the Ethics Committee of the 306th Hospital of PLA. From October 2015 to September 2016, our department used the Remebot on HICH 17 cases, and the clinical data of the patients, combined with the clinical efficacy and postoperative complications associated with Remebot, were analyzed as follows.

2 | MATERIALS AND METHODS

2.1 | Clinical data and inclusion criteria

This study included a total of 17 HICH patients treated with frameless stereotactic hematoma puncture and drainage in the department of neurosurgery of our hospital from October 2015 to September 2016. All patients were diagnosed with cerebral hemorrhage using cranial computed tomography (CT) scans, together with consciousness disorder and focal neurological signs; however, none of these patients presented with high intracranial pressure crisis, cerebral hernia, or systemic diseases with significant surgical contraindications. All patients had complete imaging and clinical follow-up data. The follow-up period was 2 to 13 months, with a median follow-up time of 5.3 months. The group included 11 men and 6 women, with the youngest being a 49-year-old patient and the oldest being an 82-year-old patient (the median age was 64.7 years old). All patients had clear histories of hypertension: nine patients had histories of coronary heart disease, eight patients had histories of diabetes, six patients had histories of stroke, five patients had histories of chronic lung disease, and three patients had histories of heart failure. The intervals between the surgery and the onset of HICH were 6 hours in six cases, 6 to 24 hours in eight cases, and 1 to 3 days in three cases. This study was conducted in accordance with the declaration of Helsinki. This study was conducted with approval from the Ethics Committee of the 306th Hospital of PLA.

2.2 | Clinical symptoms

The first symptoms upon admission for all patients were sudden headaches and dizziness, accompanied by various degrees of consciousness

Highlights

- Robot-assisted stereotactic technique provides 3D visualization and multimodal image fusion technology for assisting doctors to plan the best puncture path. The arm can freely position to the surgical target with the accuracy controlled within 1 mm.
- As for some patients with hypertensive intracerebral hemorrhage, frameless stereotactic hematoma puncture and drainage is a timely, safety, and effective treatment method which can better improve the neurological function and long-term life quality of patients
- Fully grasping the surgical indications, accurate preoperative target location and trajectory planning, intraoperative correct operation practices, and perfect postoperative treatment programs can fully develop the advantages of frameless stereotactic technologies for patients with HICH.

reduction and limb sensory dysfunction, and these symptoms progressed quickly. According to the Glasgow coma scale (GCS), four patients were scored at 6 to 8 points, eight patients were scored at 9 to 12 points, and five patients were scored at 13 to 15 points.

2.3 | Imaging performance



Before the surgery, four markers were applied to each patient's head, and then routine, cranial thin-layer axial CT scanning (layer space 2.5 mm) was performed. Ten cases were diagnosed as basal ganglia

FIGURE 1 Operation platform of Remebot

The software system can provide 3D visualization and multimodal image fusion technology to assist doctors when observing the lesions and the peripheral nerve vessel distribution and when planning the best puncture path. The binocular camera can accurately identify the patient and the markers and establish relationship mapping between the 3D image and the field, thus achieving surgical navigation. The arm can position itself freely in relation to the surgical target, and the accuracy can be within 1 mm, allowing doctors to use the operating platform to complete a variety of surgical operations.

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hemorrhage, four cases as cerebral hemorrhage, three cases as thalamic hemorrhage, and eight cases as hematoma breaking into the ventricle. The Dorian formula was used to estimate the hematoma volumes, and six cases had 20 to 30-mL hematomas, eight cases had 30 to 40-mL hematomas, and three cases had larger than 40-mL hematomas. The average hematoma volume was 34.2 mL. Some patients without clear etiologies received CT angiographies (CTAs) to exclude other bleeding factors, such as arteriovenous malformation or intracranial aneurysms.

2.4 | Surgical methods

The patient's imaging data were loaded into the Remebot software to complete the image fusion and 3D reconstruction. Then, the patient was placed in the supine position with the head fixed by one plastic pillow. After the robotic arm was reset to the zero position, it was registered at four points on the left, right, anterior, and posterior of the surgical area. The four markers on the patient's head were then registered with the probe to match the patient's image space to the operation space. After outlining the range of the hematoma, the central point of the maximum plane of the hematoma was set as the target location of the puncture needle, and the long axis of the hematoma was selected as the puncture approach, to simulate the surgical target and puncture approach. After confirming the safety of the trajectory, the robotic arm started its motion and stopped at the craniumpuncturing point, which would be marked by the surgeon. After routine disinfection and paving sterile towel, the robotic arm then re-started, according to the preoperatively set cranium-puncturing point, and when it reached the correspondent position, one sterile cover was paved together with one disinfected positioning director; after re-confirming the accuracy of the cranium-puncturing point, a 1-cm scalp was cut, and a 2.5-mm diameter hole in the bone was drilled percutaneously. Then, a No. 12 silicone drainage tube was slowly guided via the positioning director into the preset target point within the hematoma cavity; after draining the liquid hematoma, the drainage tube was closed. If the patient's conditions permitted, a postoperative CT was immediately performed to verify the location of the drainage tube and determine the evacuation conditions of the hematoma. After drainage, 3 to 5wu of urokinase diluted with 5 mL of water was injected into the hematoma cavity, and 2 to 4 hours later, the drainage tube was re-opened. This operation was repeated four to six times each day to facilitate the early discharge of the hematoma, relieving the oppression and obstruction of the hydrocephalus. The drainage tube was generally removed 3 to 5 days after the surgery, based on the cranial CT results. For those patients where the hematoma was intruding on the ventricle, if the CT demonstrated that the intraventricular high density shadow disappeared, the drainage tube was closed for 1 day; if the CT review confirmed that the ventricular systems did not expand, and the patient did not appear to suffer from the clinical symptoms of cranial hypertension, the drainage tube was removed (Figure 2).

2.5 | Evaluation indexes

The International Journal of Medical Robotics and Computer Assisted Surgery

The evaluation indexes included positional accuracy, postoperative hematoma evacuation time, mortality, and neurological improvement at discharge. The positional accuracy was calculated by measuring the distance between the preoperative planned target and the actual puncture point, through the combination of the postoperative CT images with the preoperative planning images. The activities of daily living scale (ADL) was utilized to evaluate the patients' postoperative efficacy: level I, daily life was completely recovered; level II, daily life was partially recovered or the patient can perform self-care; level III, daily life requires assistance but the patient can use crutches alone; level IV, the patient can only lie in bed while maintaining selfawareness; and level V, the patient is in a vegetative state or at near-death status. Levels I to III were recorded as good postoperative recovery, whereas Levels IV to V and death were recorded as poor efficacy.

3 | RESULTS

The operations were successfully completed for all 17 patients, with no deaths. The mean operative time was 35 minutes. One case experienced postoperative bleeding (5.9%), which was controlled by injecting urokinase and draining the hematoma; three cases experienced lung infections (17.9%). The results of the postoperative CTs showed that the drainage tubes were all accurately placed, and no off-target punctures occurred. The largest and smallest positioning errors among all 17 cases were 2.12 and 0.76 mm, respectively, with an average positioning error of 1.28 ± 0.49 mm. The distances between the end of the drainage tube and the target position were controlled within 1.5 mmin 15 patients (88.2%). The average postoperative drainage duration was 3.4 days. Before removing the drainage tube, a routine cranial CT was performed, which confirmed that 70% to 90% of the hematoma was successfully removed (Figure 3), and the mass effect either disappeared or was significantly reduced. Seven patients still presented postoperative consciousness disorders, with three cases of haziness and four cases of lethargy; the rest of the patients recovered well, without intracranial infections or tensive pneumocrania. The mean hospitalization time was 19.6 days, and the average expenditure was approximately 4700 dollars. The patients were followed up for 3 months and scored using the ADL: 10 patients returned to basic normal life (58.8%), 5 patients suffered from mild disability but were able to care for themselves (29.4%), and 2 cases suffered from severe disability and were confined to their beds (11.8%).

4 | DISCUSSION

China has a large hypertensive population, and the latest epidemiological data for China indicated that there are approximately 200 million patients with hypertension, which also demonstrates a clear increasing trend over recent years. Hypertension causes more than 7 million



FIGURE 2 Steps during the frameless stereotactic hematoma puncture and drainage to treat HICH

A-B: Attach the head mark points and design the target and puncture paths along the maximum plane and the longest axis of the hematoma. C-D: When the mechanical arm reaches the site, the minimally invasive puncture targeting the hematoma cavity is performed under local anesthesia along the preoperatively planned path.

E: The drainage tube remains in the hematoma cavity for the intraoperative suction of the partially liquefied hematoma.



FIGURE 3 CT results before and after the application of frameless stereotactic hematoma puncture and drainage A: The CT results of left basal ganglia before surgery (4 h from the onset) show that the bleeding volume is approximately 30 mL.

B: The CT results immediately after FSHPD (7 h from the onset). The drainage tube is accurately inserted.

C: The CT results 2 days after surgery (45 h from the onset). The hematoma has been removed, and only the drainage tube can be observed.

deaths worldwide each year and has become a leading risk factor for human death. Because the onset of HICH is acute and progresses rapidly, it has a mortality rate of 40% to 70%, together with a morbidity rate of 50% to 85%. HICH has become one of the most serious complications of hypertension.^{3,4} According to statistics, approximately 200 million cases of spontaneous brain hemorrhage occur in China each year, among which HICH accounts for approximately 70%.⁵ The 17 patients enrolled in this study all had clear histories of hypertension. The bleeding sites were more localized within the basal ganglia, thalamus, or unilateral lobe, and the blood supply arteries were in long-term hypertensive status, which weakens the vascular wall, forming micro-aneurysms. Therefore, under certain conditions, the vessels at these sites may bleed easily.^{6,7}

The prognosis of HICH is closely related to the amount of bleeding. A bleeding volume greater than 30 mL results in a hematoma greater than 4 cm in diameter, and the surgical indications include a significant midline shift, brain stem compression, or obstructive hydrocephalus.⁸ A traditional craniotomy can remove the hematoma and stop bleeding under direct view. Therefore, traditional craniotomies can guickly remove hematomas and reduce the mass effect; if the preoperative disease condition is serious and significant brain swelling is observed, intraoperative bone flap decompression can also be performed. However, due to longer preoperative preparation times, high anesthesia requirements, high risk of iatrogenic brain damage, and various postoperative complications, aged patients or those with cardiopulmonary dysfunctions may not be able to endure traditional craniotomies, and being older than 70 years of age is classified as a surgical contraindication.⁹ Although the application of keyhole approach craniotomy for hematoma removal results in reduced postoperative edema at surgical sites, this procedure still requires general anesthesia, the operation time is not significantly reduced, and decompression is not sufficient, which can result in postoperative skull defects and other symptoms. Bare-handed or simple hematoma positioning and puncture is another commonly used surgical treatment, characterized by simple operations and minimal invasion. However, this procedure cannot quickly remove hematomas, cannot stop bleeding, and the positioning accuracy and drainage effects are heavily dependent on the operator's experience; therefore, if the hematoma volume is small or the location is deep, the success rate of puncture can be difficult to ensure.¹⁰ Ventricular drainage is more suitable for those patients with hematomas intruding into the ventricle or for primary intraventricular hemorrhage, which can drain the hematoma and relieve obstructive hydrocephalus simultaneously.

Stereotactic surgery has the advantages of precision and microinvasion, which can significantly improve the positioning success rate toward intracranial lesions; furthermore, an accurate puncture path can be designed based on the intraoperative lesion shape and its relationship with surrounding tissues, significantly reducing surgical trauma. In 1978, Backlund applied stereotactic technology to the treatment of intracerebral hematoma for the first time and proposed the treatment concept of controlled subevacuations of intracerebral hematomas, developing a new method for the surgical treatment of HICH.^{11,12} Subsequently, this technology has been continuously improved, and the application of stereotactic techniques for the accurate targeting of deep intracerebral hematomas has been performed in many hospitals.¹³ Statistics have shown that, compared with craniotomy, stereotactic surgery can significantly increase the quality of life and survival rates in patients, while significantly reducing the rebleeding rate, postoperative pneumonia incidence, tracheotomy rate, and gastrointestinal bleeding rate.14,15 Therefore, stereotactic surgery is especially suitable for older patients or those who are unable to tolerate a craniotomy. Among the 17 patients in this study, the oldest patient was 82 years old, and this patient had a better postoperative recovery. Because this minimally invasive surgery primarily occurs only in the hematoma cavity, it can effectively remove the hematoma and avoid direct contact with ruptured blood vessels and surrounding brain tissues; furthermore, by combining hematoma aspiration with biochemical enzyme technology to rinse, liquefy, and drain the hematoma cavity, not only can the hematoma be cleared and the intracranial pressure be reduced but also intracellular cytotoxic substances can be diluted and antagonized, which can reduce the occurrence of secondary brain edema, restore the blood supply for the brain tissue in the para-hematoma ischemic penumbra, and protect the para-wound brain tissue, maximally protecting nerve function.^{16,17}

The International Journal of Medical Robotics and Computer Assisted Surgery

Traditional stereotactic surgery generally utilizes one head frame to implement positioning, which can cause pain and fear in patients; for uncooperative patients, the operations can be more cumbersome and difficult. In addition, surgical operations can be affected by the occlusion of the frame.^{18,19} The Remebot navigation and positioning system used in this study consists of one hexa-degree-free arm, one master computer, and one binocular camera, which does not require the use of the positioning frame; therefore, the operator can perform a precise operation and approach design assisted by the realtime camera positioning. In addition, the surgical view can be enlarged to avoid system and human errors, which can reduce the positioning time and improve the positioning accuracy. The results showed that the drainage tube placement paths shown in the postoperative CTs of the 17 patients were identical to the planned placement paths, and the target error was less than 1 mm. From the overall prognostic point of view, no deaths were reported in this study, and the severe limb dysfunction rate at discharge was 12.8%, indicating that the short-term prognoses of patients were significantly improved. Compared with other Chinese research data, the incidence of postoperative complications was decreased compared with that for traditional craniotomies, and the long-term quality of life was improved.²⁰ Compared with conservative internal medicine treatment methods, the average length of hospital stays and the average hospital costs in this study were significantly reduced.²¹ The reasons include the following: (a) the operation time was short, allowing the rapid relief of hematoma compression and secondary nerve damage; (b) the surgical trauma was small, reducing iatrogenic brain damage and normal intracranial environmental changes and reducing postoperative complications; (c) the drainage tube can accurately reach any preoperatively determined target sites, and 6 of 6

The International Journal of Medical Robotics and Computer Assisted Surgery

the individually designed hematoma puncture path and catheter number can be designed based on the hematoma location, shape, or other characteristics to achieve the best drainage effects; and (d) the early combination of internal medical treatment and neurological rehabilitation training after surgery is conducive to neurological rehabilitation.

Of course, stereotactic surgical treatments for HICH also have some limitations, including that they cannot stop bleeding under direct vision, and for patients who experience rebleeding within 6 hours of the onset, minimally invasive puncture technologies are subject to certain constraints. Similarly, the patients with GCS scores <6 points at admission or with nonideal puncture drainage effects should be referred for a timely craniotomy for hematoma removal. In addition, patients with relatively stable spontaneous bleeding conditions should be referred for related cerebrovascular auxiliary examinations, and bleeding caused by cerebral arteriovenous malformations is not suitable for re-puncture and drainage.

In short, stereotactic techniques are playing increasingly important roles in the treatment and mechanistic research for HICH, and the development of a frameless stereotactic technique represents a future treatment direction for cerebral hemorrhage. Fully grasping the surgical indications, determining an accurate preoperative target location and performing trajectory planning, intraoperative correct operation practices, and using the optimal postoperative treatment programs can demonstrate the advantages of these technologies.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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