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Research Article

Clinical Study of Robot-Assisted Guided Percutaneous Balloon Compression in the Treatment of Primary Trigeminal Neuralgia

Long Zhang[1], Linjie Li[1], Jianglong Han[1], Jie Xiao[1], Shengde Nong[2*]

[1]*Graduate School, Youjiang Medical University for Nationalities, Baise 530000, China.*

[2] *Neurosurgery Department of Baise People's Hospital, Baise 530000, China.*

Abstract

Objective To explore whether the robot-assisted system can significantly improve the success rate of one-time puncture and reduce the risk of puncture failure under the guidance of traditional C-arm in percutaneous balloon compression (PBC).

Methods The clinical data of 50 patients with trigeminal neuralgia aged 40 years and over admitted to the Department of Neurosurgery, Baise People 's Hospital from October 2020 to June 2023 were retrospectively analyzed. According to the surgical method, they were divided into simple C-arm guidance group (30 cases, n = 30) and robot-assisted group (20 cases, n = 20). The success rate of one-time puncture and the number of cases of ' pear-shaped ' balloon filling for the first time were recorded in the two groups, and the patients were followed up to evaluate the postoperative effect and complications. Results All 50 patients successfully completed the operation, and the success rate of one-time puncture in the robot-assisted group (100.0%) was higher than that in the C-arm guidance group (76.7%), and the difference between the two groups was statistically significant ($P < 0.05$). In terms of intraoperative balloon morphology, the rate of "pear-shaped" balloon filling at the first time in the robot-assisted group (95.0%) was higher than that in the C-arm guidance group (66.7%), and the difference between the two groups was statistically significant ($P< 0.05$).

Conclusion Robot-assisted PBC is superior to simple C-arm-guided PBC in terms of one-time puncture success rate and ' pear-shaped ' rate of balloon filling for the first time.

Keywords: Trigeminal neuralgia, Percutaneous balloon compression, Robot system,Path planning

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Trigeminal neuralgia (TN) is a common cranial nerve disease in middle-aged and elderly people. Its main manifestation is recurrent paroxysmal severe pain in the trigeminal nerve distribution area on one side of the face. Some patients are accompanied by facial spasms during attacks, which are often triggered by daily facial activities such as eating, washing the face, and brushing teeth [1]. Studies have shown that the annual incidence of trigeminal neuralgia in the world is about 4 cases per 100,000, and the annual incidence in my country is about 3 to 5 cases per 100,000. The incidence of trigeminal neuralgia in women is higher than that in men, and increases with age [2]. Trigeminal neuralgia can be divided into classic (primary), secondary and idiopathic types. Primary is the most common type, accounting for 75% of all trigeminal neuralgia cases. Trigeminal neuralgia was originally considered a functional disease. With the deepening of research, it was also found that trigeminal neuralgia is accompanied by pathological changes such as nerve degeneration, ganglion cell loss and arteriosclerotic

*Correspondence: Shengde Nong, Neurosurgery Department of Baise People's Hospital, Baise 530000, China. E-mail：tianzuowoyou@163.com

changes. However, its specific cause and pathogenesis have not yet been clarified and are still under discussion [3, 4]. The treatment of trigeminal neuralgia mainly consists of medication and surgery. The first-line drugs for treating trigeminal neuralgia are carbamazepine and oxcarbazepine, which can quickly relieve pain. However, due to long-term use of drugs, some patients may not be able to tolerate the side effects and stop taking the drugs. Long-term use of drugs may also lead to drug tolerance, requiring gradual increase in drug dosage, and even drug treatment may become ineffective. As a result, more than 70% of trigeminal neuralgia patients will sooner or later require some form of surgical intervention[5]. Currently, the main surgical treatment for trigeminal neuralgia is percutaneous trigeminal ganglion balloon compression (PBC), which is a treatment method with minimal trauma and significant effect. It can be used as the first choice of surgical treatment for some elderly and frail patients with underlying diseases or when they cannot accept microvascular decompression. Compared with other surgical methods, PBC has great advantages in low disability rate, higher patient satisfaction, and lower cost[6], and has gradually become the preferred surgical treatment for trigeminal neuralgia. Currently, percutaneous puncture of the trigeminal ganglion balloon compression is often performed under the guidance of a C-arm X-ray machine (C-arm) [7]. It is difficult to successfully puncture the foramen ovale in one go. Excessive adjustment of the puncture needle during the operation may cause damage to the nerves and blood vessels around the foramen ovale or McBurney's capsule, and increase the risk of postoperative complications. In this study, we retrospectively analyzed the clinical data of 50 patients aged 40 years and older with trigeminal neuralgia admitted to the Department of Neurosurgery at Baise People's Hospital between October 2020 and June 2023. Surgical procedures included either simple C-arm-guided percutaneous coronary intervention (PBC) or robotic-assisted PBC. In the robot-assisted PBC group, a point slightly medial and posterior to the McColl capsule was designated as the puncture target, with the center of the foramen ovale as the cranial entry point. The facial projection of the extended line connecting the McColl capsule puncture target and the center of the foramen ovale was used as the puncture entry point. This line served as the puncture path. If bony obstruction was encountered, the puncture target and entry point were adjusted appropriately to select an appropriate puncture path. Relevant data were collected and clinical outcomes and prognoses were compared between the two groups to determine optimal treatment options.

Subjects and Methods

1 Sample Selection

The clinical data of 50 patients aged 40 years and older with trigeminal neuralgia admitted to the Department of Neurosurgery at Baise People's Hospital between October 2020 and June 2023 were retrospectively analyzed. Among the 50 patients, 22 were male and 28 were female, ranging in age from 40 to 84 years, with a mean age of (62.72 ± 10.33) years. Patients were randomly divided into a simple C-arm-guided group (n=30) and a robot-assisted group (n=20). All patients signed informed consent before surgery. Information on gender, age, disease duration, preoperative VAS score, facial pain area, and underlying medical conditions for the two groups is shown in the following table (Table 1).

Table 1 Comparison of Basic Information of the Two groups of experimental Subjects

Item	C-arm Guided Group (n=30)	Robot-assisted Group (n=20)	t/χ^2	P Value
Age ($\bar{x}\pm s$, years)	63.83±8.84	61.05±12.30	0.932	0.356
Gender [n (%)]	Male 16(53.3) Female 14(46.7)	Male6(30.0) Female14(70.0)	2.652	0.103
Disease Duration ($\bar{x}\pm s$, months)	65.03±52.60	62.40±51.86	0.174	0.862
Preoperative VAS Score ($\bar{x}\pm s$, points)	6.17±0.59	5.95±0.69	1.189	0.240
Painful Facial Side [n (%)]	Left 11 (36.7) Right 19 (63.3)	Left 7 (35.0) Right 13 (65.0)	0.014	0.904
Comorbidities [n (%)]	Hypertension 8(26.7) Diabetes Mellitus 1(3.3) Cerebral Infarction 1(3.3) Heart Disease 2(6.7)	Hypertension 4(20.0) Diabetes Mellitus 0(0.0) Cerebral Infarction 0(0.0) Heart Disease 0(0.0)	1.707	1.000
Previous Surgical History [n (%)]	PBC 2(6.7)	PBC 1(5.0)	1.389	0.510

2 Inclusion Criteria

1 Patients met the diagnostic criteria for primary trigeminal neuralgia as defined in the "Chinese Expert Consensus on the Treatment of Trigeminal Neuralgia." 2. Age over 40 years. 3. Patients who had received conventional medications but had unsatisfactory results or had developed drug resistance, resulting in drug ineffectiveness, with a visual analogue scale (VAS) score > 4. 4. Patients with contraindications to microvascular decompression (MVD) or who refused craniotomy, and who were indicated for and willing to undergo PBC surgery. 5. Patients with normal communication skills were excluded. Patients with cognitive or psychiatric disorders were excluded. 6. This study was approved by the Ethics Committee of Baise People's Hospital, and all patients provided signed informed consent prior to surgery.

3 Surgical Methods

The robotic-assisted group underwent robotic-guided PBC treatment. Preoperatively, a thin-slice computed tomography (CT) scan was performed with a marker placed on the patient's head. The CT scan and a previously acquired thin-slice 1 mm 3.0T MRI image file, which met medical digital imaging and communication standards, were transferred to the robotic navigation workstation system for fusion. The puncture path was planned based on the 3D reconstructed model and CT scan: a point slightly medial and posterior to the McColl capsule was designated as the puncture target, with the center of the foramen ovale as the cranial entry point. The projection of the extended line connecting the McColl capsule puncture target and the center of the foramen ovale onto the face served as the puncture entry point, and this line served as the puncture path (Figure 1). Under general anesthesia, the patient was placed in the supine position, with the head secured to the operating table with a bandage. Robotic positioning, camera registration, robotic arm registration, and patient registration were performed. The successful puncture point

was verified with an accuracy of less than 1 mm. The robotic arm was then positioned to the surgical target, and the puncture point was marked with a marker. After routine disinfection and draping, a sharp knife is used to puncture the skin at the puncture site. Under C-arm fluoroscopy, the puncture needle is inserted through the puncture site. The robotic arm is detached from the puncture needle and returned to its original position for secondary registration. The robotic arm and patient registration are repeated to verify the puncture site. The puncture site is consistent, with an error of less than 0.1 mm (Figure 2). The robotic arm is moved to the puncture site and the puncture needle is reattached to the robotic arm. The puncture needle is inserted approximately 5 cm closer to the foramen ovale. The foramen ovale position is reconfirmed. The puncture needle is inserted approximately 3 mm into the foramen ovale. The stylet is then withdrawn. A balloon catheter is then advanced through the puncture channel approximately 15 cm until a noticeable breakthrough is felt. The distal end of the balloon catheter is confirmed under fluoroscopy. Approximately 0.6 ml of contrast agent is injected to inflate the balloon. The balloon bulges, and the C-arm fluoroscopy reveals a pear-shaped balloon (Figure 3). Pressure is applied for approximately 2-3 minutes, after which the contrast agent is released and the balloon is retrieved. The stylet is then replaced, the puncture needle is removed, and local compression is applied to stop bleeding. A sterile dressing is then applied, and the procedure is complete. The C-arm-guided group underwent C-arm-guided PBC treatment. The patient was placed in the supine position, and after general anesthesia and disinfection, a Hartel puncture path was used. The puncture was performed at a marked point approximately 2.5 cm from the corner of the mouth on the painful side (Figure 4). The foramen ovale was located using C-arm fluoroscopy. The needle was advanced approximately 5 cm through the puncture site, approaching the foramen ovale. The foramen ovale position was reconfirmed by C-arm fluoroscopy. The needle was then advanced approximately 3 mm into the foramen ovale. The stylet was then withdrawn. A balloon catheter was then advanced approximately 15 cm through the puncture channel. A noticeable breakthrough was felt. The distal end of the balloon catheter was confirmed under fluoroscopy. Approximately 0.6 ml of contrast agent was injected, and the balloon was inflated. The balloon bulged, and C-arm fluoroscopy revealed a pear-shaped appearance. Compression was applied for approximately 2-3 minutes, after which the contrast agent was released and the balloon was retrieved. The stylet was then replaced, the needle removed, and local pressure was applied to stop bleeding.

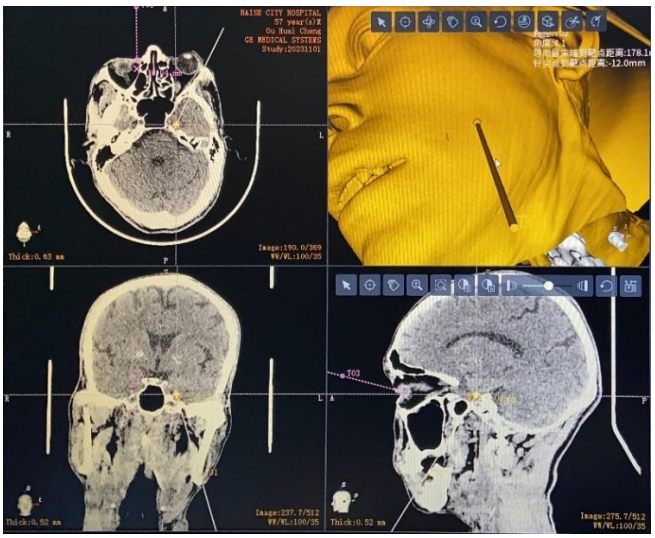

Figure 1 shows the preoperative planning using the navigation positioning planning system to navigate the workstation and plan the puncture path. The white line in the figure indicates the puncture path.

Figure 2 PBC (A) under robot-assisted guidance. The first robotic arm registration, patient registration (B). Second robotic arm registration, patient registration (C).

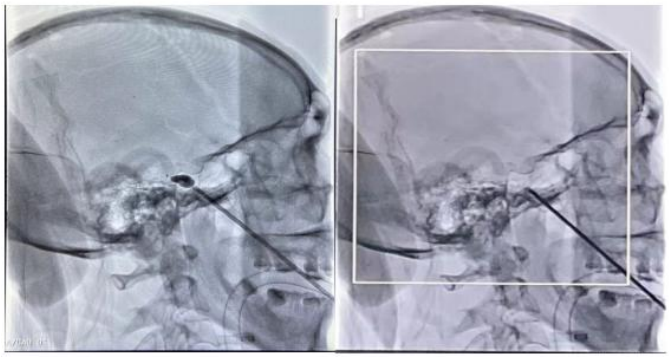

Figure 3 shows the lateral X-ray fluoroscopy view during the operation that the cannula needle successfully punctured into the inner foramen ovale (A). Lateral X-ray fluoroscopy shows that the balloon is "pear-shaped" (B).

Figure 4 shows that the PBC under simple C-arm guidance is independently guided by a C-arm X-ray machine. Puncture (A) at the marked point approximately 2.5 centimeters beside the affected corner of the mouth with a puncture needle. Confirm the position of the puncture needle under the guidance of the C-arm X-ray machine (B)

4 Data Collection

The number of successful foramen ovale punctures performed on one occasion, the number of cases with a pear-shaped balloon after the first filling, the number of C-arm X-ray scans, and the duration of the puncture procedure (time from the start of the puncture to the end of the puncture and needle removal) were recorded. Postoperative efficacy was assessed, and VAS scores were recorded within 24 hours after surgery. During follow-up, the BNI numbness score and VAS score at the last follow-up were recorded. The number of complications at the last follow-up was also recorded.

5 Statistical Analysis

Statistical analysis was performed using IBM SPSSV 26.0 software. Continuous data were expressed as mean ± standard deviation (x ± s). Differences between groups were analyzed using the t-test, with $P < 0.05$ considered statistically significant. Categorical variables were expressed as number of cases and percentage (%). Differences between groups were analyzed using the x2 test, with $P < 0.05$ indicating statistical significance.

6 Results

All 50 patients underwent successful PBC surgery, and postoperative pain was relieved. In the C-arm-guided group, 23 of the 30 patients (76.7%) achieved successful foramen ovale puncture on the first try, while the remaining 7 patients (23.3%) required repeated needle tip adjustments to enter the foramen ovale. In the robot-assisted group, all 20 patients achieved successful foramen ovale puncture on the first try (100.0%), with a statistically significant difference between the two groups ($P < 0.05$). In terms of intraoperative balloon morphology, in the C-arm-guided group alone, 20 patients (66.7%) experienced a pear-shaped balloon upon initial injection of contrast agent; the remaining 10 required contrast agent withdrawal and catheter repositioning to restore the balloon to a pear shape. In the robot-assisted group, 19 patients (95.0%) experienced a pear-shaped balloon upon initial injection of contrast agent, with 1 requiring contrast agent withdrawal and catheter repositioning. This difference between the two groups was statistically significant ($P < 0.05$). The duration of the surgical puncture (from the start of the puncture to

the end of the puncture and needle removal) was significantly shorter in the robot-assisted group (7.75 ± 1.65 minutes) than in the C-arm-guided group (10.37 ± 1.10 minutes) ($P < 0.001$). The number of C-arm X-ray scans was 23.67 ± 1.77 in the C-arm-only group and 16.15 ± 3.23 in the robot-assisted group, a statistically significant difference between the two groups ($P < 0.001$).

The average follow-up time was 5.4 months in the C-arm-only group and 5.3 months in the robot-assisted group ($P = 0.788$), a statistically significant difference ($P > 0.05$). Postoperative pain was relieved in both groups. The VAS pain score within 24 hours after surgery was compared between the two groups ($P = 0.711$) ($P > 0.05$, a statistically significant difference). No postoperative complications such as vascular injury, diplopia, ulcerative keratitis, or infection occurred in either group. However, both groups experienced varying degrees of ipsilateral facial numbness. The incidence of complications at final follow-up was lower in the robot-assisted group than in the C-arm-only group (20.0% vs 53.3%, $P < 0.05$). At the final follow-up, the BNI numbness score in the C-arm-only group was 1.63 ± 0.49, while that in the robot-assisted group was 1.50 ± 0.69, with no statistically significant difference between the two groups. At the final follow-up, the VAS score in the C-arm-only group was 2.87 ± 1.11, while that in the robot-assisted group was 1.80 ± 0.77, with a P value < 0.001 for both groups, indicating statistical significance (Table 2).

Trigeminal neuralgia is a common neurological disease in clinical practice, and its pathogenesis is not yet fully understood. The current clinical treatment system mainly adopts two modes: drug therapy and surgical intervention.

Table 2 shows the collection of experimental data and comparative analysis

Item	C-arm Guided Group (n=30)	Robot-assisted Group (n=20)	t/χ^2	P Value
Successful Puncture on First Attempt [n (%)]	23 (76.7)	20 (100.0)	5.426	0.033
Pear-shaped Balloon on First Inflation [n (%)]	20 (66.7)	19 (95.0)	4.084	0.043
Puncture Time ($\bar{x}\pm s$, min)	10.37 ± 1.10	7.75 ± 1.65	6.744	<0.001
Number of C-arm X-ray Scans ($\bar{x}\pm s$)	23.67 ± 1.77	16.15 ± 3.23	10.608	<0.001
VAS Score at 24 Hours Postoperation ($\bar{x}\pm s$, points)	0.40 ± 1.13	0.30 ± 0.47	0.373	0.711
Follow-up Duration ($\bar{x}\pm s$, months)	5.40 ± 0.62	5.35 ± 0.67	0.270	0.788
BNI Facial Numbness Score at Last Follow-up ($\bar{x}\pm s$, points)	1.63 ± 0.49	1.50 ± 0.69	0.801	0.427
VAS Score at Last Follow-up ($\bar{x}\pm s$, points)	2.87 ± 1.11	1.80 ± 0.77	3.747	<0.001
Complications at Last Follow-up [n (%)]	16 (53.3)	4 (20.0)	5.556	0.018

In the field of surgical treatment, percutaneous balloon compression (PBC) has been regarded as the preferred treatment option for patients with primary trigeminal neuralgia (especially the elderly) [8-10] due to its significant advantages such as simple operation, wide indications and low incidence of postoperative complications. This procedure uses interventional radiology technology to effectively block the trigeminal

nerve conduction pathway while demonstrating a unique neuroselective mechanism of action: selectively damaging medium and large myelinated pain nerve fibers while preserving the structural integrity of tactile fibers and unmyelinated nerve fibers [5]. This precise neuromodulation feature makes it have a significant clinical effect in pain relief. The technical core of PBC lies in the precise placement of the balloon into the McBurney capsule through the foramen ovale. The operation process can be divided into two key stages: foramen ovale puncture and McBurney capsule puncture [11]. During the foramen ovale puncture phase, the puncture needle must be precisely positioned at the foramen ovale target. Although traditional C-arm X-ray fluoroscopic guidance can improve puncture accuracy [12, 13], in cases with anatomical variations or atypical morphology of the foramen ovale [14-16], it is often difficult to achieve a successful one-time puncture using the Hartel approach, and the puncture angle must be repeatedly adjusted for success. Due to the complexity of adjacent structures such as the nerves and blood vessels around the foramen ovale, blind repeated punctures may cause damage to the nerves and blood vessels around the foramen ovale or McBurney's cyst. The robot-assisted navigation system used in this study achieved technical optimization through visual surgical planning: 1) The puncture path design abandoned the traditional Hartel anterior approach and foramen ovale target positioning strategy [9, 17, 18] and innovatively used a point in the posterior quadrant of the McElroy's capsule as the ultimate target, and the center of the foramen ovale as the entry point. The facial puncture entry point was determined by projecting the reverse extension line of the line connecting the center of the foramen ovale and the McElroy's capsule target on the face, forming the puncture path; if bony obstruction was encountered, the puncture target and entry point could be appropriately adjusted to select a suitable puncture path. 2) During the operation, dynamic registration of the robotic arm and the patient was implemented, and secondary registration of the robotic arm and the patient was performed to improve puncture accuracy and effectively compensate for target deviation caused by soft tissue deformation [17]. The results showed that the success rate of one-time foramen ovale puncture in the robot-assisted group was significantly better than that in the simple C-arm group (100.0% in the robot-assisted group and 76.7% in the simple C-arm group, $P < 0.05$), significantly reducing the risk of complications caused by repeated punctures during the operation. During the puncture of the Meckel's capsule, the precise positioning of the balloon must be ensured. If the balloon catheter is inserted too deeply, it may form an abnormal "dumbbell-shaped" shape after filling or breaking through the skull base dura mater, increasing the risk of neurovascular injury in the posterior cranial fossa [9]. In this study, the robot-assisted group, with the high-precision positioning of the navigation system, had a significantly higher success rate than the control group in presenting a standard "pear-shaped" balloon on the first filling ($P < 0.05$). It is worth noting that although the target positioning of the Meckel's capsule can theoretically guarantee a 100% success rate, there was one case that required secondary adjustment. The analysis showed that the deviation of the balloon's depth position in the Meckel's capsule may affect the balloon shape, suggesting that the spatial positioning accuracy of the Meckel's capsule still needs to be further optimized. In this study, the robot-assisted group successfully completed one special case. The patient failed to puncture under simple C-arm guidance and switched to

robot-assisted puncture, achieving a one-time accurate puncture of the foramen ovale and presenting a standard "pear-shaped" balloon shape. For special cases where the puncture path is limited due to anatomical variations of the foramen ovale, atypical shape of the foramen ovale, or other factors [19], or even only a single path to the McBurney cyst, robot-assisted puncture is definitely a surgical method with a higher success rate, shorter surgical puncture time, lower risk, and better efficacy; the robot-assisted system has shown significant advantages: its visual preoperative planning system can not only optimize the puncture path design, but also avoid bony obstructions such as the mandibular ramus or zygomatic bone through three-dimensional reconstruction, thereby improving the success rate of the operation.

Time data analysis showed that although the total operation time of the robot group increased due to the positioning and registration process of the robotic arm, the puncture time during the core operation was (7.75±1.65) minutes, which was significantly shorter than that of the simple C-arm group (10.37±1.10) minutes. This advantage is due to accurate path planning, which improves the one-time puncture success rate and reduces the number of intraoperative X-ray fluoroscopy, significantly shortening the radiation exposure time of patients and surgeons, and effectively reducing radiation levels. The shape and pressure of the PBC balloon are key factors affecting surgical efficacy and postoperative complications [20-22]. Complication analysis showed that the incidence of postoperative complications in the robot-assisted group (20.0%) was significantly lower than that in the simple C-arm group (53.3%), which may be related to the optimization of puncture angle and balloon position. These parameters directly affect balloon shape and pressure control. In the short-term efficacy evaluation, the VAS score of the robot-assisted group at the last follow-up was significantly better than that of the simple C-arm group ($P < 0.05$). However, it should be pointed out that this study is limited by the sample size and follow-up period, and it is not possible to verify the effect of robot-assisted puncture on the long-term recurrence rate. The literature suggests that PBC still maintains a moderate efficacy for recurrent trigeminal neuralgia [23], but the difference in long-term effects still needs to be verified with a larger sample. The operational efficiency of PBC is positively correlated with the operator's experience. Clinical data show that experienced physicians have a higher puncture success rate [24]. Robot-assisted PBC achieves technical optimization of simple C-arm guided procedures through visual surgical planning and precise path navigation technology: its intelligent system can automatically calculate the optimal puncture parameters, significantly reducing the technical requirements for puncture point positioning, needle angle adjustment, and balloon insertion depth judgment, thereby improving the surgical completion rate of junior physicians. This technology not only shortens the learning curve, but also reduces the incidence of operational errors through submillimeter motion control, effectively reducing trigeminal neuralgia-related complications [25]. However, it should be noted that although robot-assisted percutaneous balloon compression has significant advantages in accuracy and safety, the additional cost of the neuronavigation system (approximately an additional 15,000 yuan) leads low-income patients to prefer traditional procedures, which suggests that technology promotion needs to be combined with regional medical insurance policies for cost-effectiveness optimization. In summary, robot-assisted PBC is superior to simple

C-arm-guided PBC in terms of one-time puncture success rate, "pear-shaped" balloon rate after the first filling, surgical puncture time, number of C-arm X-ray scans and short-term efficacy. It can not only improve surgical safety and reduce the radiation level of patients and operators, but also perform visual surgical planning and accurately pre-construct individualized puncture paths. It is especially suitable for cases with stenosis of the foramen ovale, abnormal skull base bones or complex vascular and neural structures.

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