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Prospective Study

Technique of Awake Computed Tomography–guided Percutaneous Balloon Compression of the Gasserian Ganglion for Trigeminal Neuralgia

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Background: The classic percutaneous balloon compression (PBC) technique is used to complete an operation under the guidance of C-arm radiography under general anesthesia, making communication with patients during the operation impossible. It is not accurate or objective to predict the classic technique's curative effect solely by determining whether the projection of the x-ray lateral image of the filled balloon is pear-shaped.

Objectives: This study aimed to upgrade classic PBC to awake computed tomography (CT)-guided PBC technology under conscious local anesthesia and analgesia monitoring.

Study Design: Prospective clinical study.

Setting: Department of Anesthesiology and Pain Medical Center, Jiaxing, People's Republic of China.

Methods: Puncture was designed and guided by CT scanning, and the curative effect was assessed by asking the patients about what they are feeling during the operation.

Results: CT can design the puncture path and accurately guide puncture, observe the position and shape of the balloon through 3-dimensional reconstruction during the operation, and judge the curative effect according to the patient's chief concern.

Limitations: Local anesthetic analgesia is not perfect, resulting in some patients experiencing pain during surgery.

Conclusions: PBC can be completed under conscious local anesthesia and analgesia. Its curative effect and operative end standard can be determined according to the patient's chief concern. Under CT guidance, the puncture path can be designed to complete an accurate puncture and to intuitively understand the position and shape of the balloon.

Key words: Trigeminal neuralgia, computed tomography guidance, conscious sedation, percutaneous balloon compression

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Percutaneous balloon compression (PBC) of the Gasserian ganglion can effectively treat trigeminal neuralgia (1). The classic PBC technique is to complete the puncture operation under the guidance of C-arm x-ray under general anesthesia (2), and place the balloon catheter into Meckel's cave. The projection of the balloon's x-ray lateral image as being "pear shaped" is used as a marker for judging effectiveness (3). However, x-ray images are relatively blurry, and determining the foramen ovale's location during guided puncture largely depends on the clinical experience of the operator, making precision difficult.

Under general anesthesia, a patient is comfortable, but cannot communicate with the operator. Predicting the curative effect can only be based on whether the projection of the x-ray lateral image balloon is "pear-shaped." It is inevitable that patients will report pain when they wake up from general anesthesia. Therefore, our study introduced a computed tomography (CT)-guided PBC technique (4) under local anesthesia with conscious sedation and analgesia.

Methods

Preoperative Preparation

First, a diagnosis of primary trigeminal neuralgia was confirmed (5). Conservative treatment with oral medication was either ineffective or drug side effects were not tolerated. Patients were informed of the benefits and risks of various treatments for trigeminal neuralgia and were chose CT-guided PBC treatment under local anesthesia with conscious sedation and signed informed consent.

Excluding the contraindications of PBC treatment (systemic or puncture site infection, coagulation dysfunction, pregnancy, or planning to become pregnant), fasting for 6 hours presurgery, and an indwelling trocar in the vein for later use were necessary. If the procedure was performed in a nondedicated CT treatment room, the CT machine surface was wiped with a chlorine-containing disinfectant, and the CT room was sterilized and allowed to stand for half an hour. PBC-related instruments and first-aid instruments and medicines were prepared (6).

The Procedure Method

After entering the CT operating room, patients were placed supine on the CT operating table with a pillow under their shoulders in order to tilt their head back by approximately 20°. They received oxygen through a nasal catheter and underwent heart rate, blood pressure, peripheral blood oxygen saturation, and electrocardiographic monitoring. A positioning grid was placed on the face on the painful side, a head lateral positioning image was taken, and a 3-mm thick half coronal scan in sinus mode was performed (8).

The bottom edge of the scanning frame overlapped the outer ear hole (midpoint of the line connecting the chin process and incisor crown), and the upper boundary of the scanning frame reached the lower edge of the orbit (Fig. 1). The image plane containing the foramen ovale was selected as the best puncture plane in the obtained image. The puncture path was designed on this plane image, taking the inner opening of the foramen ovale as the puncture target, drawing a line to avoid the coronal process and oral cavity from this target and the intersection of the line with the facial skin as the puncture point. The distance between the puncture point and the target (the needle penetration depth) and the included angle between the line and the sagittal plane (the puncture angle) were measured using the software tools provided by the CT (Fig. 2). The CT bed was moved to the selected puncture level position, and the CT laser positioning line was opened and aligned with the positioning line.

The skin position corresponding to the grid was the puncture point, and the puncture point was marked with a marker. Subsequently, one mL of 2% lidocaine hydrochloride injection was used for local anesthesia at the puncture point of the patient, and 1 μg/kg of fentanyl citrate and 0.01 mg/kg atropine injection were given intravenously (atropine can be temporarily omitted when the heart rate is higher than 100 beats/min) so that the patient could complete the puncture treatment operation under local anesthesia and conscious analgesia monitoring (9).

Under the guidance of CT, the trocar was punctured to the inner orifice of the oval foramen according to the designed route, followed by another intravenous injection of 1 μg/kg of fentanyl and 0.01 mg/kg of atropine (atropine injection was not used if the heart rate is higher than 100 beats/min). A balloon catheter had been filled with leak detection and air had been removed from the balloon into the puncture trocar. The puncture needle core was then pulled out and the balloon catheter was slowly inserted. (If the catheter insertion resistance was high, the catheter was first withdrawn and the circuit expanded with a probe, and then the catheter was placed again).

The distal balloon part of the catheter was completely passed through the puncture trocar and entered

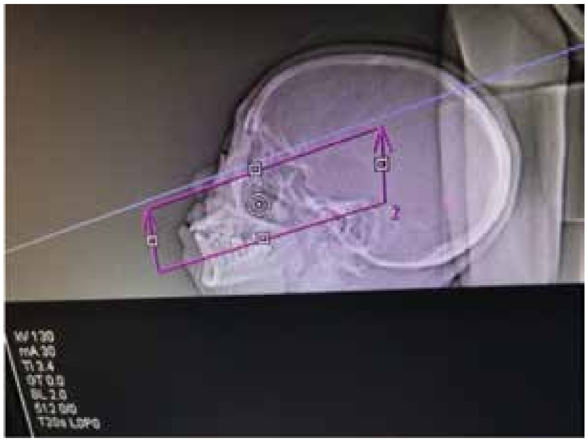

Fig. 1. *Scanning frame position: the bottom edge overlaps with the line connecting the external ear foramen (the midpoint of the line connecting the mental process and the crown of the central incisor), and the upper boundary reaches the orbital apex (the lateral positioning image of the head, and the frame surrounded by lines in the figure is the scanning frame).*

Fig. 2. *The puncture path is designed, the puncture point is located at the fourth grid of the positioning grid on this level, and the needle penetration depth and angle are measured (line segment one is the set puncture path, and the line segment length is 6.93 cm; 2 is the puncture angle, that is, the included angle between the puncture needle and the sagittal plane is 26°).*

Fig. 3. *A. The balloon catheter was inserted into Meckel's cave after the cannula was punctured into the foramen ovale. B. The balloon part of the catheter completely crosses the puncture needle cannula. The 3-D reconstruction shows that the marked point of the catheter tip was parallel with the top of the petrous cone of the temporal bone.*

Meckel's cave (Fig. 3A). CT confirmed that the catheter was tightly attached to the petrous part of the temporal bone, and 3-D reconstruction showed that the marked point at the tip of the catheter was flush with the top of the petrous cone of the temporal bone (Fig. 3B). Then, the guide wire was pulled out and about 0.3 mL – 0.6 mL of 30% iohexol contrast medium was slowly injected into the balloon (if the balloon pressure was monitored, the pressure was kept at 120 kPa – 200 kPa).

Upon timer initiation, employ pipe tee interfaces to forestall the backflow of the contrast agent and to perform CT scanning and reconstruction again to show the position and shape of the balloon (Figs. 4A and 4B). At this point the lateral positioning image can also be captured in the CT positioning image mode to observe the projection shape of the balloon. If the balloon is close to the impression of the trigeminal nerve on the petrous surface and the lateral projection of the balloon is "pear shaped," the patient was asked whether there was numbness in the trigeminal neuralgia area. Otherwise, the contrast medium was

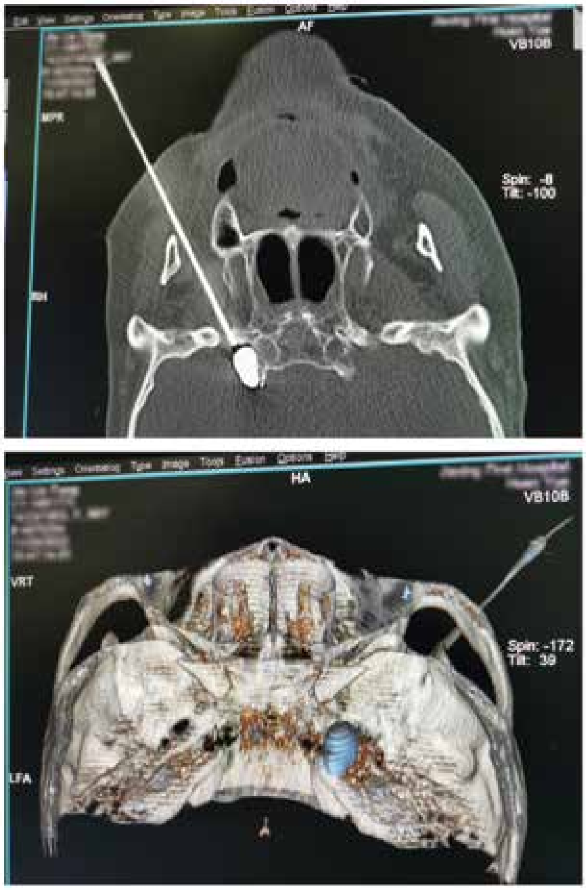

Fig. 4. *A. After the balloon was filled with iohexol, it clung to the petrous plane and the posterior lateral side of the ascending segment of the internal carotid artery; the eccentric filling was an inverted pear shape. B. 3-D reconstruction shows that the filled balloon is pear-shaped and clings to the impression of the trigeminal nerve on the petrous plane (after 3-D reconstruction, the intracranial view is from back to front; bluish gray is the filled balloon).*

emptied, and the position of the balloon catheter was adjusted before filling and compressing. When there was obvious numbness (sensation decreased and puncture pain disappeared), the balloon was slowly emptied, the balloon compression time(s) was recorded, the puncture needle was then pulled out, and the puncture point was pressed for a few minutes, ending the operation.

During the operation, the patient's blood pressure and heart rate were monitored closely. Urapidil (not US FDA approved) was administered intravenously as needed to control blood pressure from being too high. Atropine was given intravenously to prevent bradycardia (10). On the second postsurgery day, we observed whether the pain disappeared and whether there were any other discomforts or complications, and followed-up on analgesic efficacy.

Results

From April 2019 to April 2023, 248 patients with primary trigeminal neuralgia were treated with CT-guided PBC under local anesthesia and conscious sedation at our medical center. In all patients, the puncture cannula was delivered to the internal opening of the ovale foramen under the guidance of CT, and the balloon catheter was sent to the selected location through the puncture cannula. A CT scan confirmed that the distal marked point of the catheter was level with the apex of the cone.

After injecting 0.3 mL – 0.6 mL of 30% iohexol of contrast medium, the balloon was well filled, and the filled balloon compressed the indentation of the trigeminal nerve on the surface of the petrous bone (Fig. 4B) for 90 seconds – 446 seconds (261 ± 59.5).

When a patient reported obvious numbness in the primary pain area of the affected side, the procedure ended. On the second postoperative day, both the primary pain area and the nonresponsible branches of the trigeminal nerve innervation area showed different degrees of numbness.

Patients tolerated PBC treatment under local anesthesia and conscious sedation. Only 17.7% (44/248) of patients reported significant pain and limb twisting during puncture or balloon compression; however, all patients completed the treatment. Owing to the preventive use of atropine and urapidil (not FDA-approved) during surgery, no cardiovascular or cerebrovascular accidents occurred. Follow-up for one – 53 months (average, 26 months) showed a one-year recurrence rate of 13.7% (34/248) and a 3-year recurrence rate of 25.0% (62/248).

Discussion

There are many surgical treatments for trigeminal neuralgia. Among them, PBC is more advantageous than invasive surgical methods. Although trigeminal neuralgia incidence is only 4.3/100,000 (8), the pain is severe and seriously affects a patient's quality of life.

When oral carbamazepine and other drugs are ineffective or patients cannot tolerate their side effects (allergy, dizziness, and ataxia), surgical treatments such as radiofrequency ablation (RFA) (9-11), PBC, and microvascular decompression (MVD) (5) can be performed. Percutaneous RFA of the trigeminal Gasserian ganglion is a minimally invasive procedure, but years of numbness in the original pain area post-RFA can cause new problems for patients. Although MVD via craniotomy generally does not cause numbness in the original pain area, postoperative complications may include intracranial hemorrhage, intracranial infection, cerebral infarction, hearing impairment, and even surgery-related death.

PBC, similar to RFA, is treated through percutaneous puncture, which is a minimally invasive technique. The numbness of the original pain area is controllable; it is generally lighter than RFA and can subside faster. Compared to MVD, PBC is simpler and less invasive, has fewer complications, and has been increasingly favored by clinicians in recent years. The classic PBC technique involves a puncture guided by a C-arm radiograph under general anesthesia. Communication with the patient is not possible during surgery, and it is difficult to accurately judge the curative effect. In addition, the puncture of the C-arm x-ray guide is not as accurate as that of CT.

PBC can also be performed by replacing general anesthesia with local anesthesia and conscious sedation. The patient can be asked about numbness and pain disappearance in the original pain area. Numbness of the pain area and disappearance of pain were used as criteria for the end of treatment in our study.

We drew lessons from our experience (6,12-16) of completing extracranial RF therapy for trigeminal neuralgia under local anesthesia and conscious sedation. Under close monitoring and using atropine in advance to prevent bradycardia and using urapidil (not US-FDA-approved) to prevent hypertension, we have completed more than 300 cases of PBC under CT guidance. Although patients experience pain and discomfort during puncture and balloon compression, they tolerated them. During this period, blood pressure often rises due to pain and discomfort, which requires the preventive application of urapidil (not US-FDA-approved) for control.

Since the patient was awake during the entire treatment period, he could cooperate with the operator to test the effect of PBC. Compared with the classic PBC procedure under general anesthesia, the patient's numbness in the original pain area and the chief concern of pain disappearance can be used as the operation end standard (4), without relying on the so-called "pear-shaped" balloon projection under the C-arm x-ray as the predictor of curative effect and the treatment end standard, which is the norm for the classic procedure. Our novel procedure completely avoids the risk of the patient finding out that the treatment was ineffective.

CT-guided PBC has a an advantage over a C-arm x-ray or a digital subtraction angiography-guided operation. Traditional PBC is guided by C-arm x-rays under general anesthesia; however, the image accuracy of C-arm x-rays is poor; there is no 3-dimensional reconstruction function. The criterion for predicting and judging the success of the operation is whether the x-ray projection of the filled balloon on the lateral head image shows an inverted pear shape (2), which is a plane image formed by the lateral x-ray projection of the balloon; therefore, it is difficult to determine the true 3-dimensional shape of the balloon.

Puncturing the foramen ovale under CT guidance is useful because the puncture path, puncture depth, and angle can be measured with the CT's software. This makes the puncture operation more accurate and convenient, reducing the number of punctures and needle adjustments, thus effectively lowering the risk of bleeding, infection, and damage to the surrounding adjacent structures (4,6). Moreover, CT can clearly observe the depth of the implanted balloon catheter, thus avoiding complications such as diplopia or eye movement disorder caused by balloon compression involving the oculomotor and abducens nerves when the balloon catheter is implanted too deeply.

The greatest advantage of performing PBC under CT is the use of the CT's software to reconstruct the balloon scanning results. The relationship between the shape of the filled balloon, the petrous bone, and the structure of the middle cranial fossa is clearly presented (17), which is superior to the plane image obtained by projecting the filled balloon by a C-arm x-ray lateral image.

The tip of the balloon catheter should reach the top of the petrous apex of the temporal bone. If the balloon catheter is placed too deep and crosses the top of the petrous bone, the filled balloon will be squeezed into a "sub-bell" shape by the trigeminal foramen (Figs. 5A and 5B), with one side located at the impression of the trigeminal nerve in the middle cranial fossa and the other side located in the posterior cranial fossa, which may compress and damage the oculomotor nerve. At this time, the contrast medium in the balloon was released, the balloon catheter was withdrawn to the distal marked point flush with the top of the petrous apex of the temporal bone, and a pear shape appeared when the balloon was refilled (Figs. 6A and 6B), thus avoiding oculomotor nerve injury.

The key to complete PBC under local anesthesia with conscious sedation lies in adequate analgesia and prevention of the trigeminocardiac reflex (18). Before the patient entered the CT operating room, the cannula was placed in the forearm and the infusion channel was opened for intraoperative intravenous administration. After the patient was placed in the surgical position on the CT table, electrocardiogram, pulse oximetry, and blood pressure monitors were affixed. Oxygen inhalation through a nasal catheter was applied and 1 µg/kg of fentanyl citrate, a strong opioid analgesic, was administered intravenously. If the heart rate was < 100 beats/min, 0.5 mg of atropine sulfate was injected intravenously. After CT positioning and puncture path design, the puncture was performed under local anesthesia. When the puncture needle reached the oval hole, 1 µg/kg fentanyl was injected intravenously and a balloon catheter was inserted. After the CT confirmed the correct position, the balloon was filled and compressed. Changes in heart rate and blood pressure were closely monitored. If there was a sudden drop in heart rate, 0.5 mg atropine was used again, and 12.5 – 25 mg urapidil (not US-FDA-approved) can be used again to treat hypertension.

Intravenous administration of strong opioid analgesics and prophylactic static infusion of atropine before 2 strong stimulations (needle reaching the foramen ovale and balloon filling compression) can ef-

Fig. 5. *A. The tip of the catheter crosses the top of the rock cone; the balloon is filled in a "sub-bell" shape. B. Because the balloon catheter was placed too deeply, 3-D reconstruction showed that the balloon was squeezed into a "sub-bell" shape by the trigeminal foramen, which was located in the middle cranial fossa and the posterior cranial fossa, respectively.*

Fig. 6. *A. After the balloon catheter retreats to the tip of the flat rock cone at the distal end of the catheter, the balloon is filled again in a pear shape. B. The balloon catheter was withdrawn to the top of the flat rock cone at Mark point{should this be marked point?}, and the balloon was filled with iohexol in an inverted pear shape.*

fectively prevent the trigeminocardiac reflex heart rate decline during local anesthesia and conscious sedation.

In our clinical observations of more than 300 cases of PBC under local anesthesia and conscious sedation, only one patient experienced a trigeminocardiac reflex heart rate drop below 60 beats/min; no cardiovascular or cerebrovascular accidents occurred due to intraoperative hypertension. The advantage of awake PBC is that operators can interact with patients and provide a timely understanding of the procedure's clinical effects.

Intravenous fentanyl was chosen because it has both a strong analgesic effect and a certain sedative effect, and after administration patients are able to interact with operators.. Although the pain domain of patients was significantly increased after administering fentanyl, there is no concern about false positive results on analgesic efficacy because the intraoperative test mainly focuses on whether the original painful area is numb and whether the allodynia disappears. Propofol or midazolam and other nonanalgesic sedatives were not chosen to achieve intraoperative sedation because these drugs do not have a significant analgesic effect; if kept awake, patients have a significant intraoperative pain experience and extreme discomfort. If the dose of propofol is increased, the patient loses consciousness, the intraoperative interaction and coordination ability will be lost, and it is easy to have unconscious limb twisting due to pain.

Limitations

Although awake CT-guided PBC technology under conscious local anesthesia and analgesia monitoring is effective for treating trigeminal neuralgia, local anesthesia analgesia is not perfect and some patients will experience pain during surgery. Moreover, this paper mainly describes the procedure of awake CT-guided PBC; it lacks a strict double-blind control with the classic C-arm x-ray-guided PBC under general anesthesia. We suggest a multicenter, double-blind, controlled study of the classic technique and the novel technique we describe in this paper be conducted to confirm our findings..

Conclusions

PBC can be performed using CT guidance under local anesthesia and conscious sedation. The 3-dimensional reconstruction function of CT can directly visualize the relationship between the 3-dimensional shape of the filled balloon and the Gasserian ganglion of the trigeminal nerve and can change the standard of the end of treatment from the "pear shape" of the balloon in the lateral position operated under classic general anesthesia to "the patient complains of the numbness of the skin in the affected trigeminal nerve and the disappearance of the original pain," thus avoiding the risk of the patient finding that the surgery is ineffective after waking up from general anesthesia after classic PBC.

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