

The Transformation of the Balloon Shape in Percutaneous Balloon Compression for Trigeminal Neuralgia

Chenglong Sun

Zhejiang University School of Medicine

Wenhua Yu (✉ ywhsyyy@163.com)

Zhejiang University School of Medicine

Qiang Zhu

Zhejiang University School of Medicine

Quan Du

Zhejiang University School of Medicine

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Abstract

Background: The pear shape of an inflated balloon is thought to be a gold standard of a successful percutaneous balloon compression (PBC). However, neither how the balloon shape changes nor why it changes in that way (the anatomic basis) has not yet been fully described.

Methods: Radiographs from over 150 percutaneous balloon compression (PBC) cases were thoroughly evaluated. We proposed a model of changing balloon shape in Meckel's cave (MC) and 70 cases were followed up over 2 years, in which therapeutic effect was measured.

Results: We found that the balloon changed stereotypically in MC. The model that we proposed is consistent with the description of the structures of MC and its surroundings in the literature. The distinct pear (pear in MC) brought about a far better surgical result than other shapes ($p < 0.01$).

Conclusion: Our study showed how and why the balloon shape changed during PBC surgery. The model provides favorable guidance for PBC surgery.

Introduction

In 1983, a novel percutaneous technique for trigeminal ganglion compression (percutaneous balloon compression, PBC) had been described.¹ The percutaneous approach through the foramen ovale had been well developed long before this time (e.g., Harris in 1910 and Härtel's work published in German in 1914). The idea of balloon "compression" was thought to be a percutaneous modification of Taarnhoj and Shelden's "decompression" craniotomy operation. Compression was first proposed by Shelden, and he pointed out that it was not decompression but the compression that alleviated the pain.^{2,3} Mullan's great invention ingeniously combined those two aspects by using a No. 4 Fogarty balloon catheter as a percutaneous compression carrier. Since then, this approach has survived the test of time, and is still popular worldwide.

After Mullan's proposal of the PBC technique, Urculo, E., et al. studied the macroscopic changes of the technique on cadavers, providing solid evidence that a good balloon shape is ideal pear shape in Meckel's cave (MC).⁴ Although there are studies about the shape of the balloon in the PBC surgery, there is no thoroughly investigation about how and why the balloon shape changes during PBC.⁵⁻⁷ During PBC, inflated balloons may form many shapes other than a typical pear shape. In this article, we try to describe how the balloon in the MC should appear and why, and to identify which shapes are good pear shapes, which shapes are not good pear shapes and which shapes are intermediate.

Methods

The study was approved by Ethical Committee of Hangzhou First People's Hospital. All patients and/or their legal guardians gave written informed consent to treatment and collection of clinical data for

research purposes at admission. All research was performed in accordance with relevant guidelines/regulations.

Preparation and Equipment

Patients with supine position were subject to light general anesthesia. Patients' heads and their trunks were in an anatomical position, and with no head rotation or flexion. Endotracheal tube was used to carry out anesthesia.

Patients' vital signs should be closely monitored, especially during puncture and compression. In case of bradycardia or cardiac arrest, 0.5 mg atropine was prepared for IV push. Nicardipine or Urapidil was administered for high blood pressure induced by puncture or compression.

After general anesthesia, C-arm X-ray was used to obtain patients' lateral projection (Fig. 1C). The patients' position and the C-arm were kept still during the whole process.

Surgical Material and Puncturing Technique

The liver-biopsy needle with a blunted head was used to perform puncture (Fig. 1A, B). Another two longer wires with different diameters were used to perform further cannulation. We preferred modified Härtel's pathway similar to that described by De Cordoba, J.L., et al. (proposed by Henderson).^{8,9}

On lateral projection, the puncture needle appears between the mandibular condyle and hypophysial fossa. When the blunt-head needle with stylet impacts the cranial bone, the foramen ovale is identified as a soft spot in the bone. After stylet withdrawal, a thinner wire and then a larger wire are employed to perform the cannulation (as shown in Fig. 1C). A popping sensation can be felt with the wire during cannulation. When the tip of the puncture needle is positioned at the foramen ovale, we are careful not to penetrate the structure (Fig. 1C).

Balloon Volume and Compression Time

According to intraoperative pressure and the shape of the balloon, a balloon volume of 0.35 to 0.5 mL, with a mean value of 0.4 mL, and compression time 3.5 to 5 min, with a mean time of 4 min, were sufficient to achieve a good functional outcome. Before we can ensure that the balloon is in the right position (MC), we use a 0.15 to 0.2 mL balloon volume projection to find the proper position. Reinforced compression is performed for 1 to 2 mins for pain of the 1st or the 3rd branch (see below). A radiograph is taken to record of every balloon inflation, and each adjustment of the balloon is performed after the balloon is deflated.

Image Processing

The radiographs of over 150 cases were reviewed. The figures were processed or drawn by Photoshop and Adobe Illustrator.

Patient Selection and Follow-Up

Indications for PBC surgery were insufficient pain relief and/or unacceptable side effects from medication. Elderly people over 70 years old accounted for most of the cases, largely of them had previous failed surgeries or could not endure microvascular decompression (MVD) surgery. After PBC surgery, follow-up was accomplished through telephone interviews. Pain relief was defined as no trigeminal pain in patients who were not on medication.

Result

Transformation of the Balloon Shape

Before entering MC, the inflated balloon initially had a cucumber-like shape in the lateral projection (Fig. 2A1). In practice, after the balloon inflated into a pear-shape, the cucumber shape would appear by deinflating, pulling backwards and reinflating the catheter. Afterwards, when the catheter was pushed forward, it would undergo a series of consecutive shape transformations: almost round (Fig. 2A2, B1), pear (Fig. 2A3, B2, C1), dumbbell (Fig. 2B3, C2), mirror pear (Fig. 2A4, B4), down head balloon (Fig. 2C3), and balloon (Fig. 2C4). There was no smooth transition between "cucumber" and "almost round". The punctured entry point in MC could be different among cases, but the balloon could only change in a fixed pattern after it entered into MC (Fig. 7b2-b4). The descriptive words (such as "cucumber", etc.) are from here on used as the exclusive identifiers of shapes in this manuscript.

Selective Numbness

Different balloon shapes may act on different parts of the trigeminal ganglion. It was found occasionally that a more dumbbell-shaped balloon (nearer to the outlet of the MC, Fig. 3a1) and a more cucumber-shaped balloon (near the entrance of the MC, Fig. 3b2) could numb the first (ophthalmic division) or the third (mandibular division) branch (Fig. 3) respectively. There was a numbest point after the surgery, which was normally not the most painful point (Fig. 3A, B).

A Continuous Space: from MC to Porus Trigemini

When the balloon is in MC, if the balloon volume is large enough, the balloon would assume the shape of an enlarged MC and its outlet, the porus trigemini (Fig. 4e or A). As the volume or the position of the balloon changed within the range (Fig. 4a-i), the overlap of the two ends (Fig. 4B) or the whole series (Fig. 4C) would appear like the largest one (Fig. 4e or A).

The Space Holding the Third Branch Was Inconsecutive with MC

In most cases, standard cucumber shapes were failed to achieve. Normally, if the balloon became almost round, the catheter would be pulled backwards slightly, and it would slip out of the foramen ovale. Fortunately, in the three cases presented, uncommon radiographs were observed when the balloon was

pulled back slightly and inflated, after standard pear shapes were achieved (Fig. 5A1, B1 and C1), it seemed that something prevented the balloon from entering the rear space (Fig. 5B2, C2) or separated the space from MC (Fig. 5A2).

There Is Always a Pear Shape

The abnormal pear shapes (Fig. 6a1-a4) did not change in a fixed pattern and the incorrectly placed balloon would not assume the shape of MC (Fig. 6A1-A2). In contrast, after repuncture (which may be performed repeatedly), the good pear shapes change in a normal manner (Fig. 6b1-b4) and assume the shape of MC after being inflated (Fig. 6B1-B2).

An Incorrectly Placed Balloon May Produce Different Shapes

In the case of incorrect balloon position, the tip of the catheter may be restricted and distorted by the surroundings. The inflated balloon will present numerous odd shapes (Fig. 7a1-a4, b1). Some odd shapes may appear similar to ideal shapes (Fig. 7a3). When the catheter enters halfway into the MC, the shape of the balloon could initially be half correct (Fig. 7b2) before taking on a correct shape (Fig. 7b3-b4). To note, most cases result in good pear shapes after repuncturing, and they may be different from each other (Fig. 7A, B).

Table 1
Patient Characteristics of 70 Patients Undergoing PBCs

Characteristics	No. of Cases (%)
Sex (male/female)	21/49
Age at treatment (years)	
Median	72
Range	31–93
Preoperative duration of TN (months)	
Median	75
Range	1-240
Branch of pain (%)	
V1	4 (5.7)
V2	21 (30)
V3	18 (25.7)
V1 + V2	8 (11.4)
V1 + V3	1 (1.4)
V2 + V3	14 (20)
V1 + V2 + V3	4 (5.7)
Previous surgery for TN (%)	
Craniotomy (MVD, CPA tumor)	27 (38.6)
Minimal invasive techniques	27 (38.6)
Multiple treatments	12 (17.1)
Non	4 (5.7)

V1, V2, V3 = first, second, and third branches of the trigeminal nerve.

Minimal invasive techniques: PBC, glycerol rhizotomy, electrocoagulation, gamma knife.

Multiple treatments = Craniotomy + Minimal invasive techniques.

Table 2
Results of 70 patients after PBC

	pain relief	recurrent
distinct pear shape	52	7
pearlike and other shapes	6	5

p = 0.00665, chi-square test

Table 3
Side effects and complications in 70 patients
after PBC

Side effects and complications	Cases (%)
Facial numbness	
Mild	23 (32.9)
Bothersome	14 (20)
Mastication weakness	4 (5.71)
hemihypogeusia	3 (4.3)

Outcome and Complications

70 out of 150 cases were successfully followed up over 24 months. Patients' characteristics

are presented in Table 1. Most of the patients (66/70) had previous operative history (minimal invasive or craniotomy). 59 out of 70 cases got distinct pear shapes (Table 2). Distinct pear is defined as balloon that locate in MC and will transform in the stereotype as described above. The result of the patients with distinct pear was significantly better than those patients without ($p < 0.01$). No serious complication was observed. Ipsilateral facial numbness was the most common complication (37/70) and other complications are listed in Table 3.

Discussion

The radiographs were carefully selected from over 150 PBC cases. Most of the cases that resulted in the optimal pear shape were a one-time success and of no reference value. The cases presented here mostly required much more adjustment. Normally, if a non-pear-shaped balloon hasn't been achieved, another puncture would be immediately performed again (sometimes the puncture might be repeated for several times), which has been proven to be a safe approach. That is different from that described by Mullan, and may not be the policy for most physicians, who "repeated a few days later."^{1,6}

A lower volume of 1.5-2 mL was used to test the position of the balloon. In previous reports, most often, the volume of injected contrast is 0.7 mL. In Mullan's original article, the volume was 0.75 ml. In our view,

that is more than enough. In our cases, the average inflated volume of 0.4 ml is much lower than what is generally reported.^{1,6,10} Sometimes, even with a small volume, the numbness is devastating. The procedure, including balloon volume combined with compression time, was acceptable over one-year of follow-up. The balloon volume should differ from person to person, according to the stature, balloon pressure, and other variables. This observation is beyond the scope of this study.

The dural structure of the trigeminal nerve delineates the contour of the MC and its potential connection. MC is formed by continuous dura mater, which isolates its contents from the middle cranial fossa below and the temporal lobe above.^{11,13,14} The dural sheaths cover the 3 major divisions of the trigeminal nerves and extend far beyond the points that the divisions join the ganglion. For the mandibular branch, the dural sheath leaves the middle fossa through foramen ovale and fuses with the epineurium extracranially (Fig. 8A).^{11,13}

For a correct placement, a fully inflated balloon should include two tunnel-like ends and one large belly. One tunnel end should target the sheath of the mandibular branch and the other should target the porus trigeminus, while the large belly should target the main part of the MC. However, all of the fully inflated balloons, that we have observed or that have been reported, have never assumed that kind of shape. It seemed there was a septum between the sheath of the third branch and MC. As a result, the fully inflated balloon can only take on the shape of one large belly (MC) and one tunnel end (porus trigeminus, Fig. 8B). Indeed, there is such a septum named the cribriform area by Li, Y. et al.¹¹ The cribriform area also explains why the space accommodating the third branch is difficult to enter (Fig. 5), and there is no smooth transition between a cucumber and an almost round shape (Fig. 8b, c and Fig. 2A1-A2).

For partially inflated balloons, they assumed the shape of the space holding them. Therefore, there were cucumber, almost round, pear and dumbbell (or hourglass) shapes in the cavity. Except for the cucumber, the last three shapes can smoothly change from one to another through the adjustment of the catheter. The mandibular branch, the ganglion and the nerve root each has their own share of space in the MC. The last two have much less effect on the balloon shape; however, the mandibular branch would interact with the balloon to deforms its shape. As a result, the cucumber shape is not such a typical shape. Furthermore, the dural structure of the third branch, whether or not the dural sheath stretches out of the foramen ovale, is still controversial.¹¹⁻¹³

The forepart of the tentorium and the dural band superior to the opening of the MC (that is, the porus trigeminus) stretches out into the subarachnoid cisternal space. If the balloon catheter goes beyond the porus trigeminus and partially enters the subarachnoid space, then the dura will bend the head of the balloon downward.^{12,15} At this position, part of the balloon is still in MC, so the inflated balloon looks like a mirrored pear shape (a mirror image of the right pear, Fig. 8f). In addition, if the balloon completely exits the porus trigeminus, the obstruction of dura would cause a down-head balloon (Fig. 8g), and then followed by a balloon (Fig. 8h).

Based on thorough literature review, a model of the dural architectures of MC and its potential connection were proposed in order to explain the variations of the balloon shape (Fig. 8). The model could well explain the variation and transformation of the balloon shape and its potential connection in the MC. It is an informative reference for balloon adjustment. For example, if someone intends to achieve a standard pear shape, but the inflated balloon is an hourglass shape or a mirror pear shape (Fig. 8e, f), the balloon must be deflated followed by slightly removing the catheter backwards, and then reinflate the balloon. Situation changes if an almost round shape (Fig. 8c) is achieved, the balloon should be reinflated in a forward position.

Surprisingly, we found that balloon compression towards the two ends selectively numbs the third branch (the proximal end, towards the cucumber) and the first branch (the distal end, towards the dumbbell). Because we always perform standard pear compression before cucumber shapes or dumbbell shapes as reinforcements, most patients would still complain of hemifacial numbness instead of a localized numbness. The numbness was acceptable for most patients, so it is not a good option to perform selective compression alone. However, for this study, good pear compression is a necessity for a PBC. Brown, J. A. described a method specialized for different divisions of pain: on anteroposterior view and using trigeminal impression as a reference, for first, second (or multidivisional), or third division pain, the stylet should be aimed the trigeminal impression medially, centrally and laterally, respectively.¹⁶ This method of using different MC entry points (for different angles) to realize the selectivity was very likely to be the same as what we made use of different shapes of the balloon. The results also coincide with the anatomical structure of the trigeminal nerve.^{8,17}

As mentioned above, the cucumber shape was difficult to obtain normally. If a cucumber shape was failed to achieve, the catheter would be pulled backwards and maintain a little tension when the balloon was almost round. This method was used as an alternative to reinforce compression of the pain from the third division. For pain from the first division, we would slightly push forward the catheter, and, when a good pear shape was achieved, a more "hourglass" pear shape would immediately appear.

Although there exist articles identifying correlations between different balloon shapes and the patients prognosis,^{6,10} we believe there only one true pear shape. The shapes of the pears may be subtly different from one another, but true pear shapes change in a stereotypical way. Parts of the dura mater around MC could be easily detached from its surroundings, so the incorrectly placed balloon would assume many peculiar shapes. However, fake pear shapes that were quite similar to standard pear shapes did not change stereotypically; in many instances, they had twisted balloon ends (Fig. 7a3).

We have given far more detailed description about the balloon shape changing in PBC. A good outcome of PBC had long been related to a pear shape balloon, so was our study. The model we presented here was based on circumstantial evidence from fluoroscopy. There are still shapes that we were unable to positively classify. The dural structure of MC (may rupture as a result of puncture) and the petrous ridge and angulation of the trigeminal nerve could lead to the variation in the balloon shape that cannot be

directly observed during PBC. ¹⁸ Sometimes, the experience of the physician remains the determining factor.

Conclusion

Meckel's cave, its inlet, and its outlet force the inflated balloon to take on a variety of shapes. Going forward, the shapes are as follow: cucumber, almost round, pear, dumbbell, mirror pear, down-head balloon, and balloon. Different balloon shapes may act on different parts of the trigeminal ganglion and cause selective numbness based on trigeminal nerve division. These findings offer a good reference for PBC surgery in clinical events.

Declarations

Conflicts of Interest:

The authors declare no conflicts of interest.

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Figures

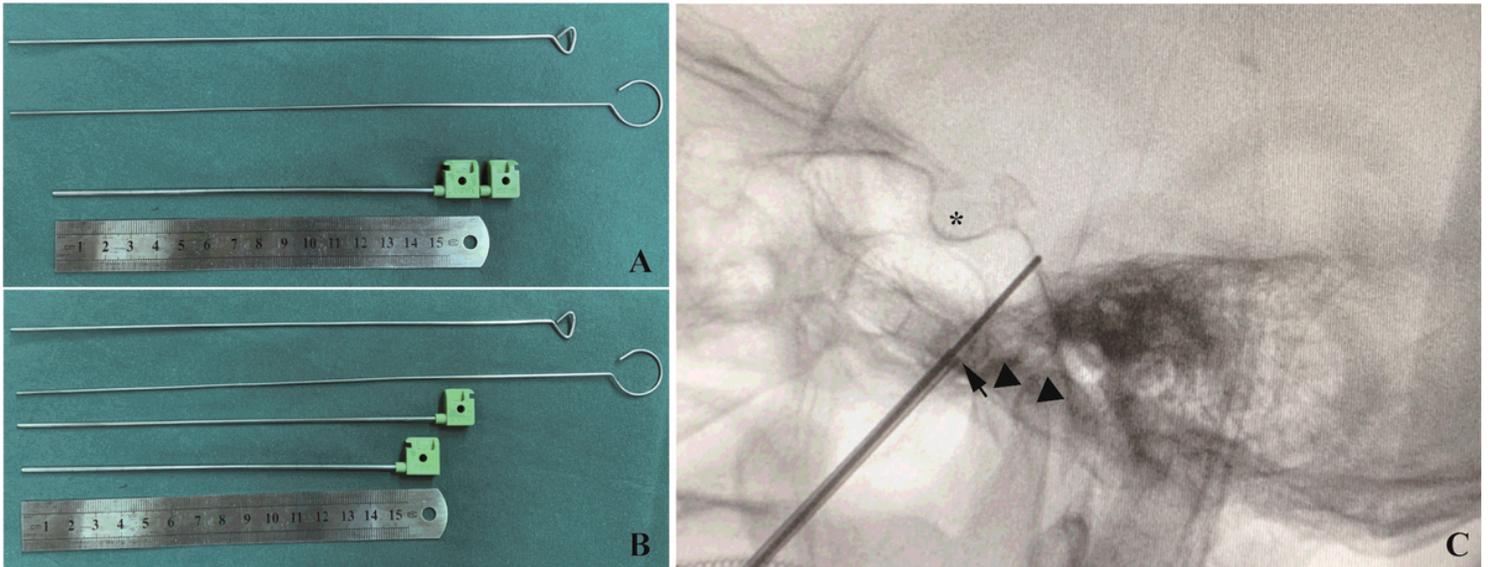


Figure 1

Puncture kits and a lateral projection of a PBC surgery. A: PBC Puncture kits. From bottom to top: ruler (as scale), head-blunted liver-biopsy needle with stylet in, thinner needle of blunted head, needle of larger diameter. B: PBC Puncture kits with the stylet out. C: Lateral projection cannulation: The tip of the puncture needle (cannula) is at the foramen ovale (arrow) but does not penetrate. The tip of the thinner needle comes across the clivus on the projection; the puncture sets are between the mandibular condyles (black triangle) and hypophysial fossa (*).

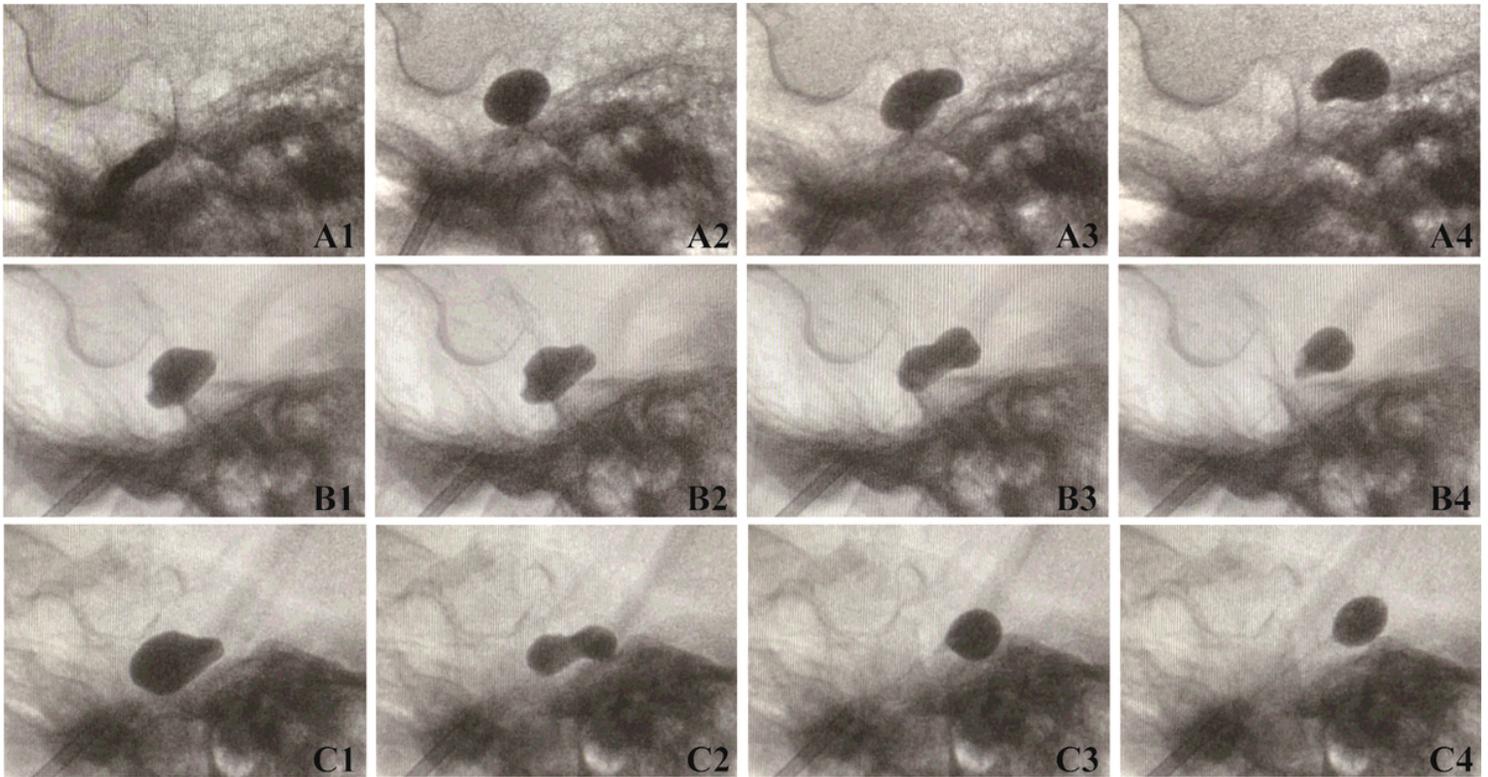


Figure 2

Transformation of the balloon shape in MC. For each row (A, B, C), the figures are from the same patients. As when pushing the balloon catheter forward, the balloon shape changed in a stereotypical manner: cucumber(A1), almost round (A2, B1), pear (A3, B2, C1), dumbbell (or hourglass, B3, C2), mirror pear (A4, B4), down-head balloon (C3), balloon(C4). (It should be noted that the balloon may not change in that orders in the actual procedure.)

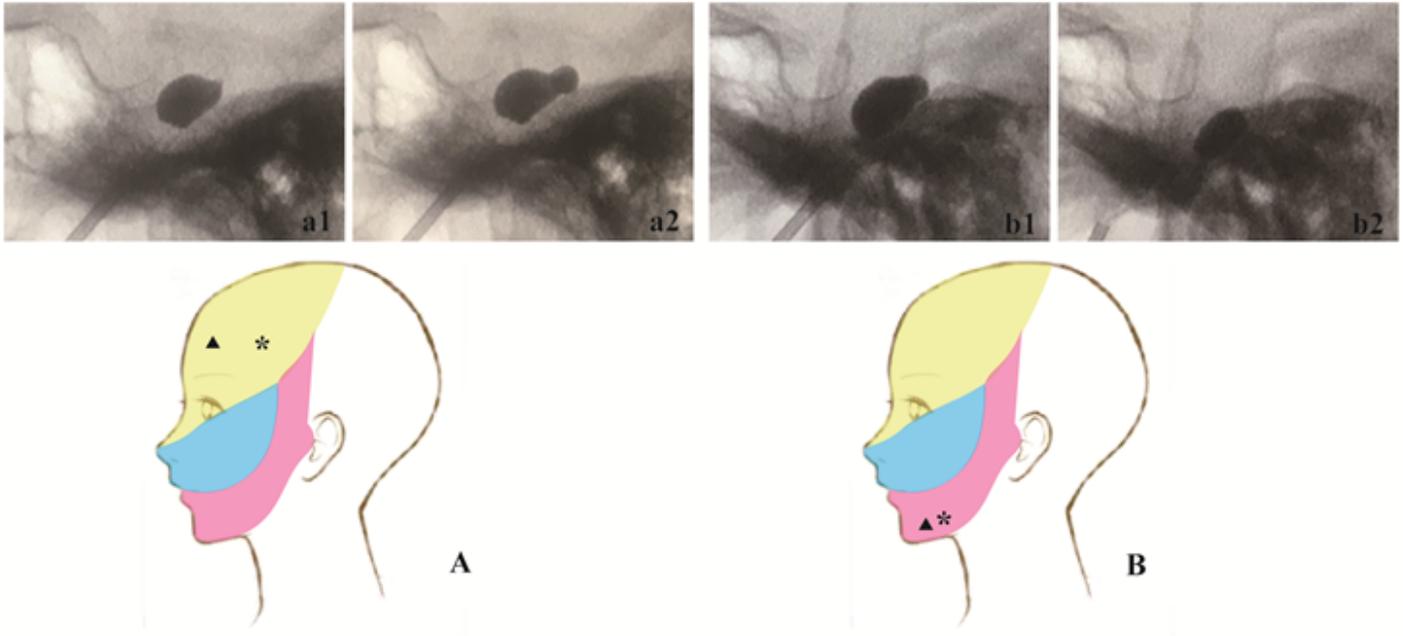


Figure 3

Selective numbness. After we performed the routine pear shape (a1, b1) compression (3-4 min): A: For the first branch pain (marked with ▲), the more dumbbell-shaped balloon (a2) reinforced compression (1-2 min) could give the selective effect of the first branch numbness (marked with *). B: The cucumber-shaped balloon (b2) reinforced compression (1-2 min) could contribute to selective numbness of the third branch (*). The pain region(▲) and the numbness region(*) did not overlap.

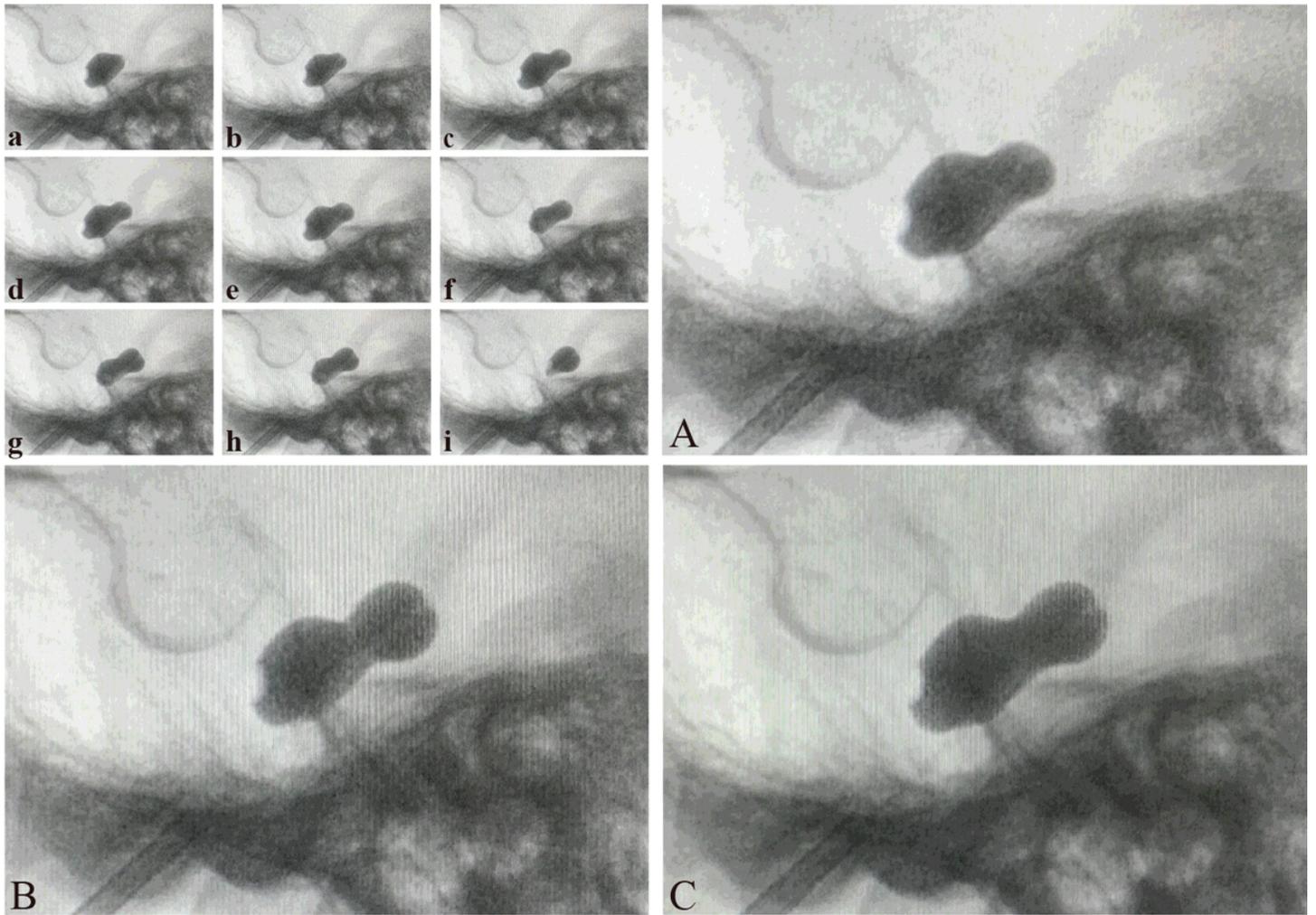


Figure 4

MC and its outlet is a continuous space. a to i are a consecutive series of pictures during a PBC surgery (From the same patient of Fig. 2 B). A is an enlargement of e; B is an overlap of a and i; C is an overlap of a to i. Note that A, B and C are almost the same.

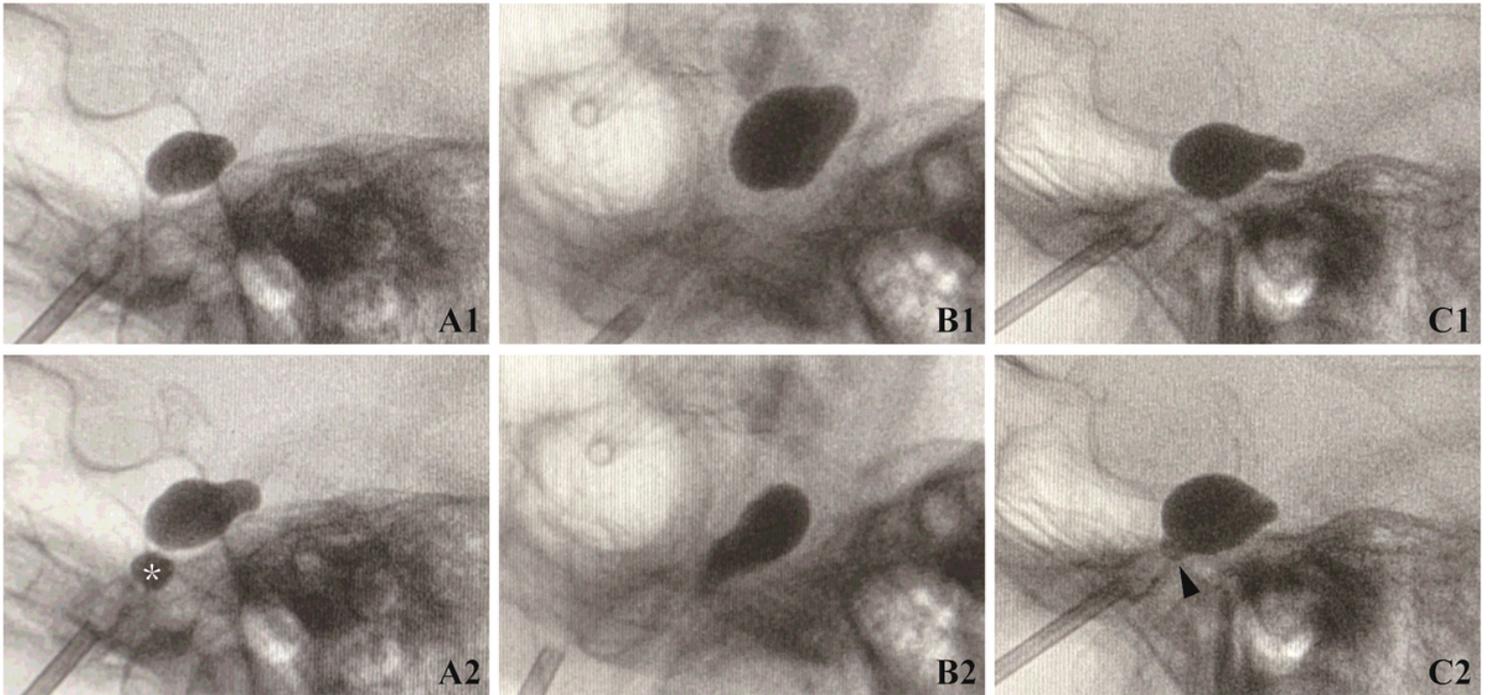


Figure 5

The space that is accommodating the third branch is not contiguous with MC. The sets A, B and C are from three patients. A1, B1 and C1 are standard pear shapes. For the purpose of third branch reinforced compression: When inflated, A2 had a disconnected tail (*). When pulled back and reinflated, B2 had sharp triangle tail; C2 only got a small butt (arrow head).

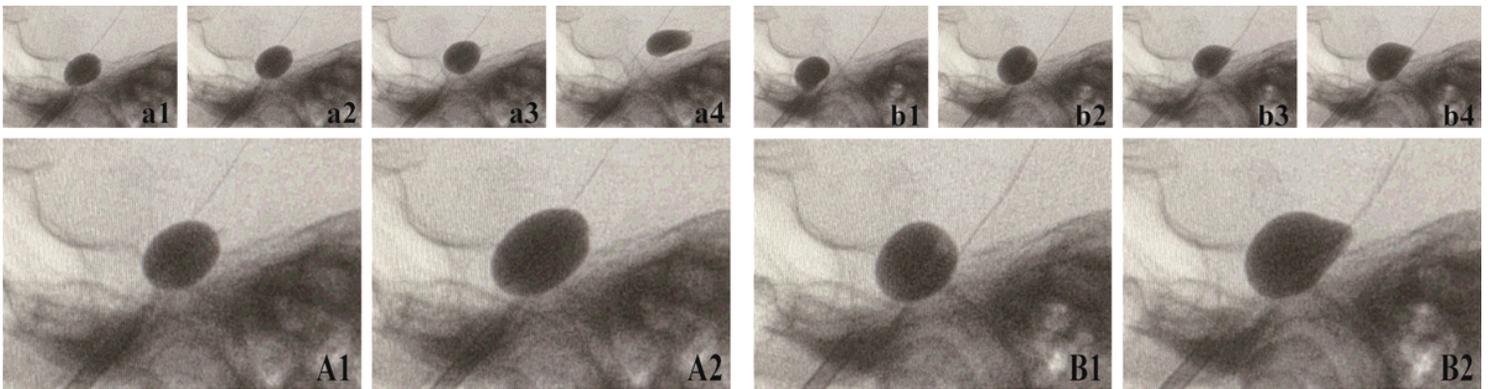


Figure 6

There is always a pear shape. Both set A (a) and set B (b) are from the same patient during one PBC surgery. Set A (a), the balloon catheter was not in the right anatomic space (MC), When the catheter was pushed forward, the balloon did not change in a standard mode (a1 to a4). When inflated, the balloon just got larger but did not assume a correct shape (A1 to A2). In contrast, set B (b) was in the correct position, the balloon changed in a correct manner (b1 to b4) and was inflated to a correct shape (B1 to B2).

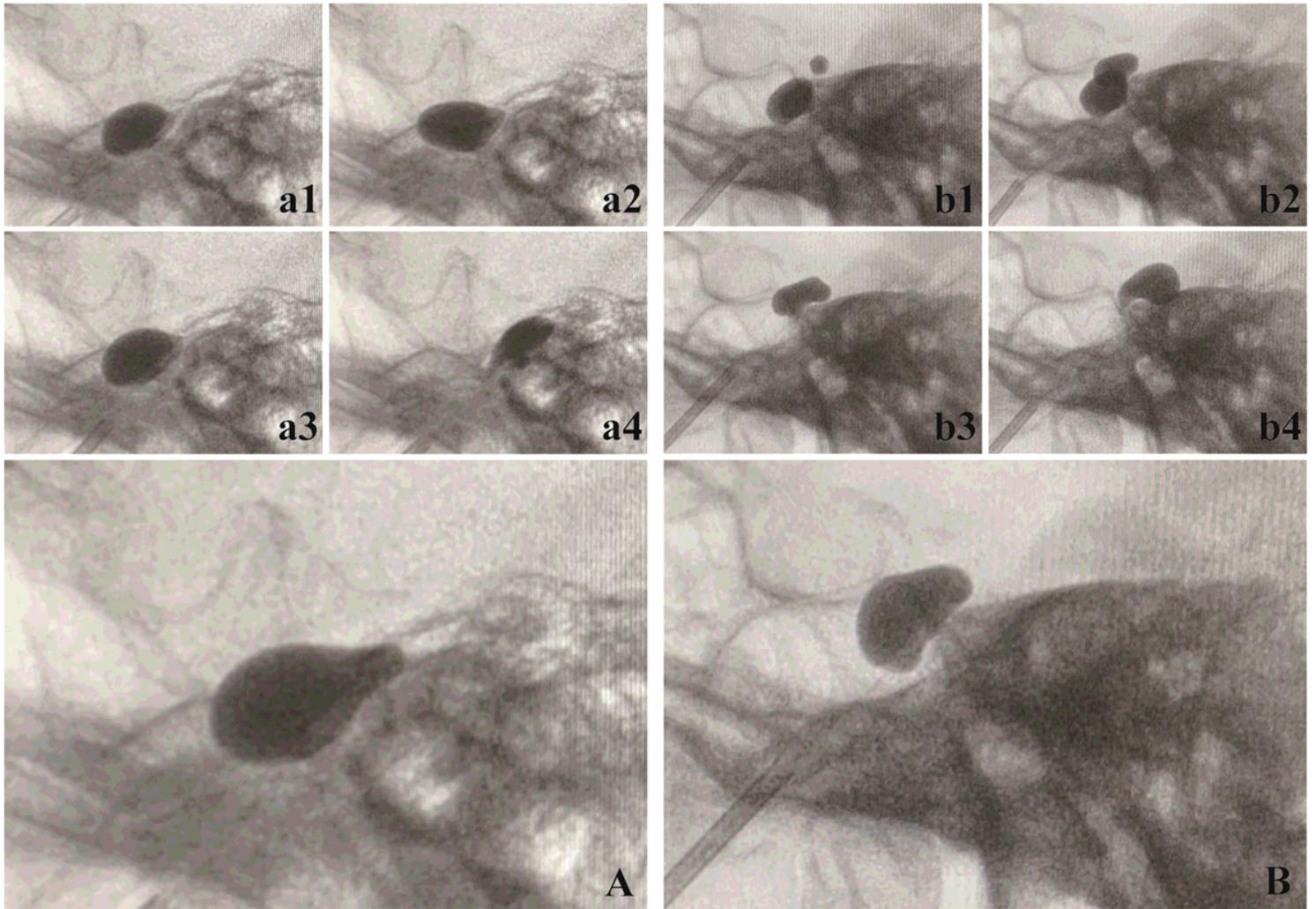


Figure 7

An incorrectly placed balloon resulted in unsatisfactory pear shapes. Set A (a) was from one PBC patient. a1 to a4 are not correct pears (although a3 seems very likely to be right, it is disguised with a distorted end), A is the correct pear shape of the patient. Set B (b) is another patient. b1 is not correct. The upper part of the balloon of b2 is in the correct space, causing the following b3 (dumbbell) and b4 (mirror pear) change in a correct mode (because the entry point was in the half way of the MC(b2), one could not get a correct pear shape by adjusting the catheter). B is the correct pear of the case.

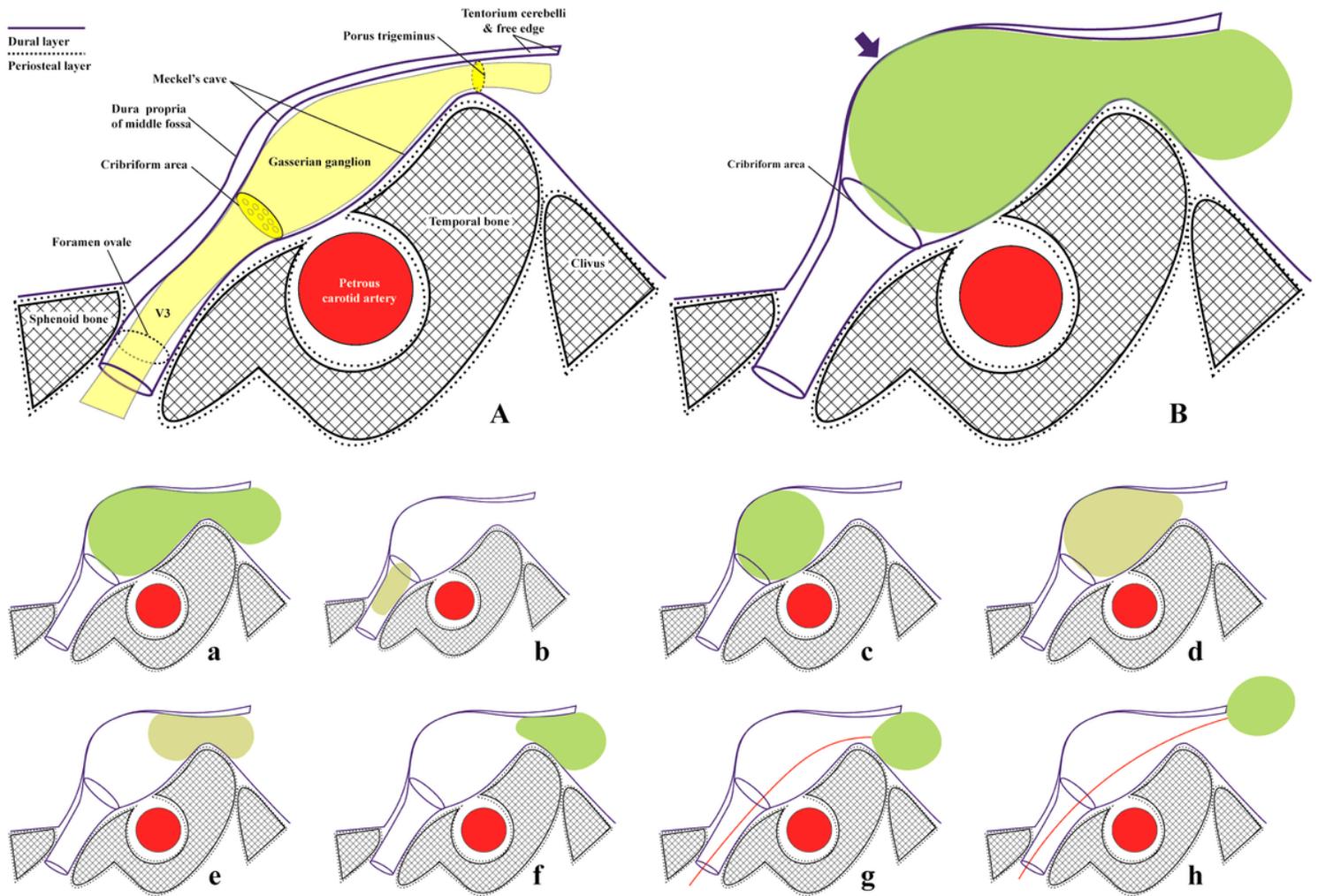


Figure 8

Schematic showing of MC and balloon changes (Redrawn from Joo, W., et al. Based on the work of Joo, W., et al., Li, Y., et al. and Janjua, R.M., et al 11-13. A: Oblique coronal section between the porous trigeminus and the foramen ovale. The superior surface of Meckel's cave is formed by double layers of dura matter: meningeal dura (dura propria of middle fossa) and periosteal dura (inner layer of MC). The periosteal dura can be seen lining the bone intra- and extracranially and forms the sheaths of nerve branches. Cribriform separates MC from the peripheral nerve sheaths. B: A balloon fully inflated in MC. (the large belly of the balloon, blue arrow). a: a small version of B. b: cucumber. c: almost round. d: pear. e: dumbbell (or hourglass). f: mirror pear. g: down head balloon (as a result of the block of tentorium cerebelli). h: balloon. Refer to Fig. 2. Red line, balloon catheter.