

## Original Article

## Technical considerations and outcome assessment in retrogasserian balloon compression for treatment of trigeminal neuralgia. Series of 901 patients

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### Abstract

**Background:** The aim of our study was to describe the retrogasserian balloon compression (RGBC) procedure with some personal tricks and to assess the long-term results.

**Methods:** Between 1985 and 2012, 901 patients, suffering from refractory trigeminal neuralgia (TN), underwent RGBC procedure in our department. Concerning the surgical technique, the introducer was in close contact with the posterior extremity of the horizontal plate of the palatine bone and had the direction of the bisector of the angle clivus-superior edge of the petrous bone on an X-rays sagittal view. No metallic material was inserted intracranially. The balloon was inflated with 0.7 cc of contrast medium for 6 min.

**Results:** At 1 month follow up, appreciable pain relief was obtained in 835 patients (92.7%). At 1 year, results were excellent in 605 patients (67.1%), satisfactory in 109 patients (12.1%), poor in 57 patients (6.3%), fair in 66 patients (7.3%), whereas recurrences were observed in the remaining 64 patients (7.2%). At mean follow up of 16,5 years, 559 (62%) patients remained pain free. Twenty six patients (2,8%) continued to experience severe pain. Recurrences occurred in two hundred and fifty patients (27,8%). Fifty two of them were operated on a third time and 22 underwent four procedures.

**Conclusion:** RGBC is an appropriate and effective procedure for treatment of refractory TN, ensuring a long lasting pain relief predicted on three factors: pear shape of the balloon, its volume, and duration as mentioned earlier.

**Key Words:** Balloon compression, foramen oval, percutaneous approaches, recurrences, trigeminal neuralgia

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## INTRODUCTION

Trigeminal neuralgia (TN), also called “suicide disease”, is one of the most painful complaints of the human kind. The appropriate first line treatment is carbamazepine.

When it becomes refractory, surgery is indicated. The surgical armamentarium dedicated to relieve TN has enlarged and put the neurosurgeon in a hesitating position to choose the appropriate technique. In 1983, Mullan<sup>[30]</sup> first described balloon compression (BC)

consecutively to the operative data of Shelden<sup>[33]</sup> reported in 1955. These have established that the decompression of the fifth nerve associated to a compression with a blunt dissector was preferable to its simple decompression. In 1995, Brown<sup>[12]</sup> demonstrated that large myelinated axons, involved in the sensory trigger, are mostly injured while small myelinated fibers are relatively preserved during this mechanical compression. The ideal goal of the procedure was analgesia without side effects. The technique remains today as one of the most popular surgical procedures practiced worldwide. Through this study, we shall detail the surgical technique and evaluate the quality of the postoperative pain relief.

## MATERIALS AND METHODS

### Patients

The pre-and postoperative clinical data of 901 patients treated with BC for refractory TN within a 27-year period, from 1985 to 2012, were reviewed from clinic patient registers. All our patients suffered from drug-resistant idiopathic TN or complained of carbamazepine side effects. Two other procedures, radiofrequency of thermorhizotomy and microvascular decompression, were also performed in our department. The first was considered in case of TN affecting the territories of the maxillary or and mandibular branches with integrity of the ophthalmic nerve's area, the second was recommended for the young patient, aged below 45 years, without co-morbidity. The patient's consent was obtained after informing him that the first technique required an awake and cooperative patient during the procedure that can lead to discomfort for him, whereas for the second, a craniotomy was mandatory. The patient population consisted of 476 females and 425 males. Their age ranged from 16 to 88 years with a median age of 54.5 years. Four patients underwent previous radiofrequency (RF) of rhizotomy, no patient was operated for performing microvascular decompression. The distribution of the neuralgia concerned the right side in 533 patients, the left side in 365 cases, and was bilateral in 3 patients. The V2 territory, alone or associated to another area, was the most involved: 798 cases (78.62%).

### Devices, anesthesia, and head's position

The procedure required a C-arm fluoroscope and the following materials: A hollow metallic introducer (HI) gauge 14 with a sharp tip, swathed in a silicone catheter (SC) allowing the blood or the cerebrospinal fluid (CSF) to escape in case of vessel injury or dural tear. To inflate the balloon, a number 4 Fogarty catheter (FC) and a contrast medium (CM) as Iopamiro are also required. Surgery was performed under brief general anesthesia with intratracheal intubation. The patient was in supine position, the neck and thorax slightly flexed with the nose in a top position.

This allows us to obtain a strict sagittal X-ray during the following surgical steps.

### Surgical procedure

We distinguished two steps:

#### *First, the foramen oval cannulation*

For this percutaneous approach, three skin landmarks were marked on the cheek [Figure 1]. They defined the classical Hartel's route: The first (1) corresponds to the location of the skin puncture: 2.5 cm lateral to the angle lip. The second (2) is on the inferior edge of the zygomatic arch, 3 cm anterior to the external auditory canal. The third (3) is on the line joining the first point to the pupil on the inferior edge of the orbit. After surgical cleaning of the affected hemi face, the HI was inserted in 1 as described above [Figure 2]. During its moving forward, we should have in mind that the direction of the foramen oval (FO) cannulation is superposable to the intersection of two planes, one lateral including the points 1 and 2, and the other sagittal including the points 1 and 3. Three anatomical structures will be successively traversed: The cheek, then the pterygo maxillary fossa, and finally the FO.

The neurosurgeon's index was in close contact with the internal side of the cheek. It guided the introducer in order to avoid the penetration of the oral cavity [Figure 2]. However, bleeding can happen deeper in the pterygo maxillary fossa through the HI or within the cheek. This is due to the injury of branches of internal maxillary artery or of the veins of the pterygoid venous plexus [Figure 3]. So, the procedure should be stopped, whereas the hemostasis is obtained by external compression of the cheek. In this case, the surgery is re-performed 1-2 weeks later.



**Figure 1:** The three landmarks of the Hartel's route on the right hemiface: The first corresponds to location of the skin puncture: 2.5 cm lateral to the angle lip. The second is on the inferior edge of the zygomatic arch, 3 cm anterior to the external auditory canal. The third is on the line joining the first point to the pupil on the inferior edge of the orbit

Multiple endeavors were sometimes useful to penetrate the FO. Bone landmarks [Figure 4], depicted on biplane fluoroscopy, help to correct or to confirm the HI steering:

The first is the close contact of the introducer with the projection of the posterior extremity of the horizontal plate of the palatine bone observed on the X-rays sagittal view.

The second is the direction of the HI, which should be the bisector of the angle composed by the superior edge of the petrous bone and the clivus [Figure 4].

The crucial step was the engagement of the FO, recognizable by seeing and feeling the masseter muscles shrinking. The advancement of the HI was interrupted from that moment, in order to avoid its penetration inside the skull.

#### *Second, the inflation of the balloon*

The HI was withdrawn while the plastic catheter was tenderly pushed up 3-4 mm toward the Gasser ganglion. CSF drops, coming from the trigeminal cistern, may exit through the stylet at the skin orifice. The FC's balloon was filled with CM in order to check its patency and to realize the air evacuation.

Next, the FC was inserted into the hub of the SC so that the extremity corresponding to the deflated balloon was located beyond. Once the optimal location of the balloon was ensured under fluoroscopy with a first small inflation with 0.3 cc of CM, the definitive inflation of the balloon was finally achieved with 0.7 cc for 6 min.

When the BC started, bradycardia with diminution of the blood pressure can occur. The last sagittal X-rays [Figure 5] showed the thin SC and the balloon in a pear shape on both sides of the clivus: The body and the stalk of this image correspond, respectively, to the Gasser ganglion and to the trigeminal plexus. When the duration mentioned earlier was slipped away, the balloon was deflated and all the material removed. The patient was discharged after one overnight stay.

#### **Endpoints and quality of the pain relief**

Pain relief was evaluated for four times after surgery: The first day, one month, one year, and at the time of the last follow-up. We distinguished five categories: Excellent (totally pain free without any medication), satisfactory (occasional pain controlled with 1-2 tablets of carbamazepine per day), poor (attenuated pain with severe hypoesthesia or dysesthesia), failure (continuance of pain as in the preoperative period), and recurrence (return of the characteristic lightning pain after a remission period superior to one month).

The mean length of the follow up period was 16.5 years.

## **RESULTS**

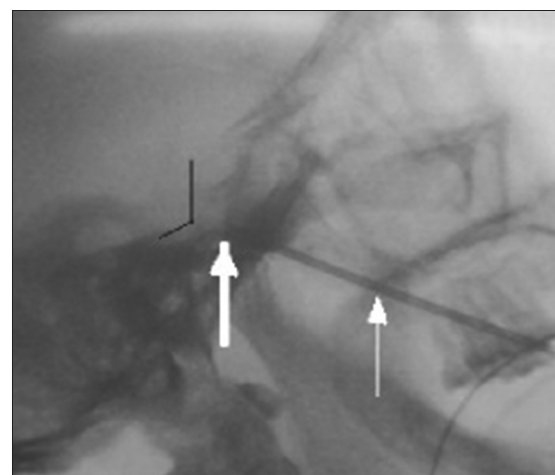
The day following the surgery, of the 901 patients, 819 (91%) were totally pain free [Table 1]. Some of them,



**Figure 2: Skin puncture for balloon compression in a patient under intubation and general anesthesia**



**Figure 3: Three-dimensional volume computerized tomography depicting the vessels in the pterygo maxillary fossa, especially the internal maxillary artery (short yellow arrow), the foramen oval (long yellow arrow) after resection of the zygomatic arch and the coronoid process of the mandible (black arrows)**



**Figure 4: Sagittal X-rays showing the metallic hollow introducer (HI) in close contact with the posterior extremity of the horizontal plate of the palatine bone (thin white arrow) and at the level of the foramen oval (thick white arrow). In black lines: The clivus and the superior edge of the petrous bone**

who presented with CSF leak during the procedure, complained from transient headaches during few days. Failures were observed in 82 cases. Their causes are detailed in Table 2.

One month later, after excluding cases of failures, we observed that among the 835 cases (92.6%), 655 were excellent (72.7%) while 180 (20%) were satisfactory.

At one year follow up, excellent results were observed in 605 patients (67.1%), satisfactory in 109 (12.1%), and poor in 57 other (6.3%). Of the 835 patients, the first recurrences occurred in 64 cases (7.2%).

After a follow up period of 6 months to 27 years according to the cases (average: 16.5 years), 432 patients (47.9%) were complete pain free, whereas results were satisfactory in 127 patients (14.1%). Twenty-six patients (2.8%) complained from severe in lieu of dysesthesias which were the main presenting symptom of our poor results. On the whole, in patients who underwent one procedure, acceptable outcome including excellent and satisfactory results [Figure 6] were estimated to be, respectively, 92.7%, 79.2%, and 62% after 1 month, 1 year, and 16.5 years of follow up. Pain recurrence was observed in 250 patients (27.8%) who required another procedure: 1 in 176 cases, 2 in 52 cases, and 3 procedures in 22 patients.

The transient and peculiar complications of retrogasserian balloon compression (RGBC) [Table 3], which resolved usually within 3-6 months, were: A well centered area of hypoesthesia on the affected territory in 806 cases (89.4%), usually well accepted by the patient, masticatory weakness in 98 cases (10.8%), otalgia and or hypacusis in 92 cases (10.2%), and temporo mandibular joint pain in 20 cases.

The other and common morbidity to all the percutaneous approaches, observed in this series of BC, included perilabialis herpes in 66 cases (7.3%), cranial nerve palsy

in 11 cases, diminished corneal reflex in 8 cases, and rhinorhea in 3 cases.

The definitive complications consisted of disabling dysesthesias in 26 patients (2.8%), moderate-to-severe hypoesthesia in 13 cases, and unilateral blindness in 2 patients.

Four patients developed infectious complications, which impacted greatly on their outcome; there were two cases of abscesses, one intracerebral and another one located in the cheek and meningitis in two cases. These different complications are listed in Table 4.

We deplore, in the beginning of experience, one death following a brainstem injury, which was due to the penetration of the metallic introducer beyond the FO.

**Table 1: Quality of pain relief in 901 patients operated on according to the RGBC technique**

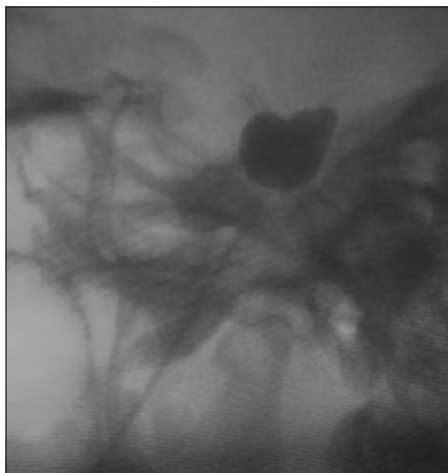
|              | 1 <sup>st</sup> postoperative day (%) | One month (%) | One year (%) | 16.5 years (%) |
|--------------|---------------------------------------|---------------|--------------|----------------|
| Excellent    | 819 (90.9)                            | 655 (72.7)    | 605 (67.1)   | 432 (47.9)     |
| Satisfactory |                                       | 180 (20)      | 109 (12.1)   | 127 (14.1)     |
| Poor         |                                       |               | 57 (6.3)     | 26 (2.8)       |
| Failure      | 82 (9.1)                              | 66 (7.3)      | 66 (7.3)     | 66 (7.3)       |
| Recurrence   |                                       |               | 64 (7.2)     | 250 (27.8)     |
| Total        | 901                                   | 901           | 901          | 901            |

RGBC: Retrogasserian balloon compression

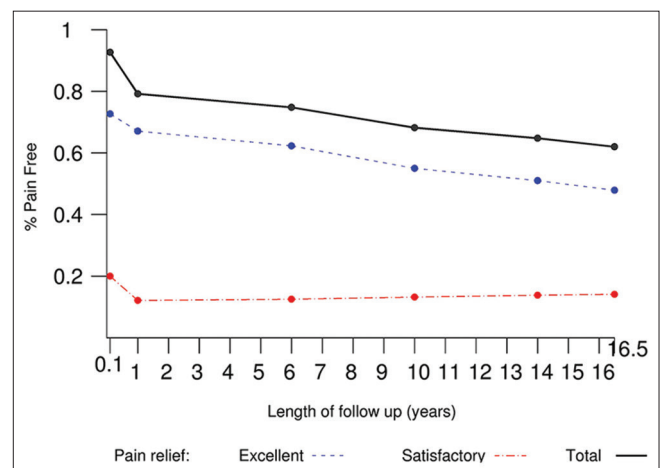
**Table 2: RGBC technique: Causes of failure**

|                               |    |
|-------------------------------|----|
| Cheek hematoma                | 26 |
| Impossibility to cross the FO | 14 |
| Atypical balloon shape        | 30 |
| Atypical trigeminal neuralgia | 12 |
| Total                         | 82 |

RGBC: Retrogasserian balloon compression, FO: ???



**Figure 5: Lateral view X-rays revealing the thin silicone catheter (SC) and the ideal pear shape of the balloon**



**Figure 6: Graph analysis demonstrating duration of pain relief in 901 patients after percutaneous balloon compression. X-axis denotes pain free survival in years and Y-axis denotes rates of pain-free patients**



## DISCUSSION

Although numerous reports were previously published on this topic,<sup>[1,4-6,11,13,17,18,24,26,28,34,35]</sup> it seemed important to us to first report these technical notes with some personal tricks, and, in contrast, to review the results of our experience in RGBC during the past 27 years.

The number of patients treated (901) and the long follow up (from 6 months to 27 years) conferred singular characteristic to this report.

### Anesthetic considerations

Taking advantage of our experience with patient's cooperation in radiofrequency thermorizotomy procedure, the first 20 patients underwent the surgery without intubation but under brief narcosis. Unfortunately, the procedure was extremely painful. We abandoned this technique which was beneficial neither for the patient nor for the surgeon.<sup>[3]</sup> The general anesthesia was then adopted.

### Surgical considerations

Concerning the surgical technique, we observed, in the beginning of experience, failures in cannulation of the FO. Their number decreased, day after day, utilizing an intraoperative C-arm fluoroscopy as frequent as necessary to check the correct trajectory of the HI. Its projection was in close contact with the posterior extremity of the horizontal plate of the palatine bone. This first radiological landmark is of a great importance for the safety and effectiveness of the procedure. By observing it in sagittal view, accurate puncture of the FO was facilitated. As mentioned earlier, the second landmark is the guidance of the HI, which should be the bisector of the angle formed by the clivus and the superior edge of the petrous bone. To reduce the bad steering, some authors recommended for targeting the use of three-dimensional fluoroscopy,<sup>[32]</sup> neuronavigation<sup>[8]</sup> or three-dimensional axial tomography reconstructions.<sup>[27,38]</sup>

In so far, this direction is correct, the explanation of the impossibility of crossing the FO refers to an unusual anatomy characterized by spine, tubercle,<sup>[22]</sup> or ossification of ligaments near the FO.<sup>[36]</sup> These are the pterygospinous (ligament of Civinni) and the pterygoalar (ligament of Hyrtl) ligaments. Our rate of 1.5% (14 cases) of technical failures was similar to those of the literature of about 3%: Lichtor<sup>[26]</sup> reported, in 1990, 3 cases of a series of 100 cases, whereas Skirving<sup>[30]</sup> reported, in 2001, 9 cases of 522 procedures.

For the procedure's safety, we should have in mind another important anatomical structure, the lateral wall of the cavernous sinus, close neighboring area to the Meckel's cave.<sup>[20]</sup>

The clever maneuver of pushing the SC beyond the FO with no intracranial metallic material avoids the premature balloon rupture or other redoubtable issues as injury of any cranial nerve or blood vessel.<sup>[10,15,16,21,25,37]</sup>

### Balloon compression

As to the inflated balloon, the main point was to define the ideal volume and duration of the inflation. In this way, we have changed the parameters increasing the inflation and reducing the compression time. Before our current attitude, they had been 0.4 cc and 9 min for a first subgroup of 20 cases, then 0.5 cc and 7 min for the same number of patients,<sup>[3]</sup> and finally 0.7 cc and 6 min for the last 861 patients.

The location and the shape were the two other carefully checked parameters. The best location on a sagittal view X-rays is pre-and postclival corresponding to the compression of the Gasser ganglion-triangular plexus junction. Since the publication of Mullan<sup>[30]</sup> in 1983, all the authors emphasized on the predictive power of the pear shaped balloon on the outcome, which results in longer pain relief.<sup>[4,18,23]</sup> In our series, it was obtained in 85% of the series (766 cases) during the first procedure and decreased to 60% in case of recurrences. Among the remaining 15% (135 cases), the shape was sometimes circular or oval and less frequently in hourglass [Figure 7]. We were apprehensive of this first type form of balloon, which was synonymous with location without close compression of the Gasser ganglion or of the root. However, excellent results can also be achieved<sup>[19,29]</sup> with generally a short duration of pain with precocious recurrences. In our series, 30 cases of poor results were imputed to this balloon shape. On the other hand and paradoxically, pain relief was usually achieved in case of hourglass or "8" shape.

**Table 3: Transient and peculiar complications after RGBC technique**

|                               |             |
|-------------------------------|-------------|
| Hypoesthesia                  | 806 (89.4%) |
| Masticatory weakness          | 98 (10.8%)  |
| Otalgia and or hypoacusia     | 92 (10.2%)  |
| Temporo mandibular joint pain | 20 (2.2%)   |

RGBC: Retrogasserian balloon compression

**Table 4: Definitive and transient complications observed after RGBC technique**

|            | Perilabialis herpes | Oculomotor nerve palsies | Corneal reflex diminished | Rhinorrhoea | Severe dysesthesias | Severe hypoesthesia | Unilateral blindness |
|------------|---------------------|--------------------------|---------------------------|-------------|---------------------|---------------------|----------------------|
| Transient  | 66 (7,3%)           | 11                       | 8                         | 3           |                     |                     |                      |
| Definitive |                     |                          |                           |             | 26                  | 13                  | 2                    |

RGBC: Retrogasserian balloon compression

With regard to literature data, volume and time varied from 0.4 to 0.9 cc and from 1 to 9 min. For Lichtor,<sup>[26]</sup> the volume was usually 0.7 cc but occasionally up to 1 cc and the duration 1 min. As for Kouzounias,<sup>[23]</sup> the balloon was inflated with about 0.7 ml of CM until it resembled a pear or dumbbell shape, and remained inflated for 60-120 s.

Bergenheim<sup>[6]</sup> insisted on the clearly defined pear shape, which usually appeared after injection of 0.5-0.7 ml of contrast material, the balloon remaining inflated for 1.5-3 min.

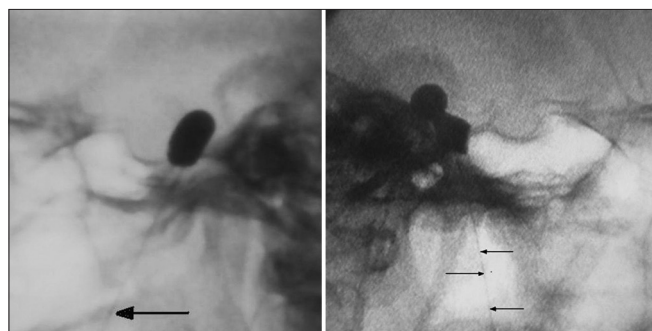
Chen<sup>[13]</sup> reported that patients treated with 90 s of compression did better than those treated with 70 s without apparent added complications. Gutzwiller<sup>[18]</sup> published her results on a series of 122 patients and concluded that a compression time of less than 90 s was a strong predictive factor of pain recurrence, consequently the optimal BC is equal to or longer than 90 s.

It was and it remains our policy based on this fact that a longer compression time results in longer symptom-free periods and a well acceptable rate of recurrences. In the meantime, this duration could lead to significant rates of hypoesthesias and masseter muscle weakness; However, our precaution to have no intracranial metallic material, close or inside the trigeminal nerve should certainly reequilibrate the balance of these complications due to the ablative technique.

In recent work published by Brown<sup>[9]</sup> the authors studied the mean intraluminal compression pressure and the mean duration of compression, which were, respectively,  $1160 \pm 62$  mmHg and  $1.15 \pm 0.2$  min. They conclude that morbidity rates were lower when the pressure monitoring was used.

### Pain relief considerations

On the results point of view, the analysis of outcome showed that of the 82 cases of immediate failures, 26 were due to pain induced by huge hematoma in the cheek, which obliged us to stop the procedure. One week



**Figure 7: Lateral view X-rays revealing an unacceptable shape of the balloon despite the close contact of the silicone catheter (SC) with the posterior extremity of the horizontal plate of the palatine bone (black arrow)**

later, a repeated surgery was performed in all of them, with success in 16 cases. In 14 other cases we failed to cross the FO. In 30 cases, the cause was an atypical circular shape of the balloon. In the remaining 12 cases of unsuccessful surgery, the motive was errors of diagnosis as common cluster headaches, glossopharyngeal neuralgia, or temporo mandibular disorder. Over time, recurrences happened. They do not equate with failure; they are inevitable if intolerable adverse effects are to be minimized.<sup>[31]</sup> Most of the time, the patient was pain free between two procedures.

Table 5 summarizes data observed in our series and in similar ones. Our rate (27.8%) tallied with those of Lichtor<sup>[26]</sup> or with those of Skirving,<sup>[35]</sup> which showed, on a series of 496 patients, a recurrence of pain in 31.9% over a mean length of follow up of 10.7 years, whereas dysesthesias occurred in 3.8% of the entire series. In the report of Liu<sup>[28]</sup> on 276 cases, recurrences occurred in 14 patients after a mean follow up of 18.7 months. Of a series of 206 patients reported by Baabor,<sup>[5]</sup> 35 patients (15%) had developed recurrences after a 3-year follow up.

Of a series of 185 patients, Chen<sup>[13]</sup> reported 36 patients (29.5%) who had recurrent symptoms within 5 years and a total of 46 patients (37.7%) with recurrent symptoms during the mean length of the follow-up period, which was 8.9 years.

Three salient drawbacks, generally transient, are specific of this technique and could compromise the comfort's patient or his quality of life during the first weeks: Masseter muscle weakness, consecutive to injury of the motor root of the trigeminal occurs in approximately 10% of the cases;<sup>[15]</sup> hypoesthesia of the affected territory due to a long compression time was frequent and should be expected on the first post operative day. However, it is more tolerated than recurrence or dysesthesia.<sup>[1,5,6,24,30]</sup> Usually, these two side effects were reversible over a period of 6-12 months. On the other hand, the rarity of severe sensory deficits including dysesthesia, anesthesia dolorosa, and corneal anesthesia<sup>[9,13,17,18]</sup> confers to this technique a main advantage compared with the other percutaneous techniques morbidity.

**Table 5: RGBC technique: Recurrence rates reported in the data literature**

| Author  | Number of patients | Follow up   | Rate of recurrences (%) |
|---|--------------------|-------------|-------------------------|
| Lichtor and Mullan, 1990 <sup>[23]</sup>      | 100                | 1-10 years  | 28                      |
| Brown, 1996 <sup>[11]</sup>                   | 141                | 22 months   | 26                      |
| Skirving and Dan, 2001 <sup>[30]</sup>        | 496                | 10.7 years  | 31.9                    |
| Liu <i>et al.</i> , 2007 <sup>[25]</sup>      | 276                | 18.7 months | 5                       |
| Baabor and Perez Limonte, 2011 <sup>[5]</sup> | 206                | 3 years     | 15                      |
| Chen <i>et al.</i> , 2011 <sup>[14]</sup>     | 185                | 8.9 years   | 37.7                    |
| Our series, 2013                              | 901                | 16.5 years  | 27.8                    |

RGBC: Retrogasserian balloon compression

Buzzing, consequence of the paresis of the tensor tympani muscle is the third frequent complaint. Oculo motor nerve palsies were also reported<sup>[7,16,21,37]</sup> and are certainly due to mislocation of the balloon more than 5 mm beyond the clivus on a sagittal view or through the superior orbital fissure. We have not observed postoperative vascular complications as carotid cavernous fistula. They remain rare.<sup>[10,25]</sup>

Other advantages of the procedure were the exceptional keratitis following an abolished corneal reflex and the absence of the anesthesia dolorosa or its exceptional supervening.<sup>[2,11,13,26,34,35]</sup>

## CONCLUSION

On the whole, we emphasize on the importance of the skin and imaging landmarks, crucial steps to penetrate the FO and on the pear shape of the balloon, which is a sine qua non condition for good results. According to the immediate postoperative success equal to 91% and the long lasting pain relief observed in 62% of the series, we can assert that RGBC is an effective and safe procedure in patients of any age. However, the best candidates are patients with neuralgia affecting the V1 territory, old patients, those in poor medical condition but also those suffering from a very intense pain and consequently who cannot cooperate during surgery. Likewise we should take into account the short mean total procedure time of 30 min, the short hospital stay of 24 h, and its cost efficiency.

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