Prospective Evaluation of Nasopharyngeal Intubation During Radiofrequency Thermocoagulation of the Trigeminal Ganglion

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Aims: To investigate whether nasopharyngeal airway (NPA) intubation could reduce the risk of complications caused by radiofrequency thermocoagulation (RFT) of the trigeminal ganglion. **Methods:** From November 1, 2014 to May 1, 2015, 200 patients treated with sedation (combination of sufentanil and propofol) were randomly divided into two groups, one in which NPA intubation was used (intervention group) and one in which it was not used (control group). The primary outcome was the frequency of hypoxemia, and secondary outcomes were the frequency of hypotension, nasal mucosa damage, corneal numbness, masticatory weakness, palsies of other cranial nerves, and intracranial hemorrhage. Statistical analyses were performed by using the Statistical Package for Social Sciences version 19.0. A P value < .05 was considered to reflect statistical significance. Differences in the frequencies of adverse events between the two groups were assessed by using Fisher exact test. **Results:** Five patients in the intervention group showed minor nasal mucosa injury ($P = .027$). Hypoxemia (19 vs 3, $P < .001$), corneal numbness (12 vs 4), and masticatory weakness (11 vs 3) occurred more frequently in the control group than in the intervention group ($P < .05$). No significant differences in the incidence of hypotension or palsies of other cranial nerves were observed between the two groups ($P > .05$). **Conclusion:** NPA intubation can reduce the frequency of hypoxemia and complications related to the thermocoagulation of the trigeminal ganglion with minor risks for nasopharyngeal injury. *J Oral Facial Pain Headache 2018;32:e28–e33. doi: 10.11607/ofph.1785*

Keywords: *airway, hypoxemia, radiofrequency thermocoagulation, trigeminal neuralgia*

Classical trigeminal neuralgia is one of the most severe pain conditions experienced by humans. Radiofrequency thermocoagulation (RFT) of the trigeminal ganglion is a minimally invasive and effective procedure,[1] but patients suffer intolerable pain during RFT. Therefore, it is essential to sedate and anesthetize the patient to facilitate the coagulation process.[2] A commonly used regimen for sedation (such as during gastrointestinal endoscopy) involves the combination of propofol with opioids.[3,4] Although safe, this regimen is not completely free of risk of complications such as respiratory depression or glossoptosis, which in some cases can lead to severe or even fatal complications.

Assisted ventilation through a full-face mask is the first choice for treatment if respiratory depression or glossoptosis occurs.[5] However, lifting the patient's jaw to apply assisted ventilation may displace the thermocoagulation needle tip so that the RFT may lead to complications such as corneal numbness, injuries to other cranial nerves, and intracranial hemorrhage.

Intubation through the nasopharyngeal airway (NPA) is recommended for patients who experience respiratory complications due to glossoptosis caused by sedation,[6] particularly in patients who are unconscious or semiconscious.[7] The intubation tube maintains patency of the airway and thereby prevents airway occlusion, hypoxia, and asphyxia.[8] In addition, there is no need to lift and hold the patient's jaw to assist ventilation, thus avoiding possible displacement of the thermocoagulation needle.

NPA intubation cannot be routinely applied due to the risks of complications such as nasal mucosal injury.[9] Thus, the aim of this study was to determine whether NPA intubation could reduce the risk of complications caused by RFT of the trigeminal ganglion. The primary outcome measure was the frequency of respiratory depression. Secondary outcome measures included the occurrence of nasopharyngeal damage, hypotension, corneal numbness, masticatory weakness, palsies of other cranial nerves, and intracranial hemorrhage.

Materials and Methods

Study Participants

In accordance with the ethical principles of the Declaration of Helsinki, the current study was designed as a prospective, randomized controlled clinical trial conducted from November 1, 2014 to May 1, 2015. The study protocol was approved by the Human Ethics Committee of the First Affiliated Hospital of China Medical University (No: 2014-124). All patients read the informed consent form and agreed to the therapeutic protocol. This trial was registered with chictr.org.cn (number ChiCTR-IPR-15005754). Consent forms were signed by patients before their inclusion in the study.

Inclusion and Exclusion Criteria

Eligible patients were between 30 and 90 years old and presented classical trigeminal neuralgia (involving the second and/or third branch of the trigeminal nerve). The diagnostic criteria for classical trigeminal neuralgia were as follows[10]: *(1)* paroxysmal attacks of pain lasting from a few seconds to 2 minutes and affecting one or more divisions of the trigeminal nerve; *(2)* pain with at least one of the following characteristics: intense, sharp, superficial, or stabbing precipitated from trigger areas or by trigger factors; *(3)* similar attacks in the individual patients; *(4)* no clinically evident neurological deficit; and *(5)* not attributed to another disorder. To exclude pain attributed to another disorder, such as a tumor, hematoma, or demyelinating diseases, all patients received magnetic resonance imaging (MRI) of the brain. After a systematic neurologic examination to rule out other causes, the pain physician made a diagnosis of classical trigeminal neuralgia based on the above criteria.

The study included patients for whom carbamazepine therapy (from 200 to 600 mg per day) had to be discontinued because it did not lead to sufficient pain relief or because they could not tolerate the side effects and patients not willing to undergo pharmacologic treatment. None of the patients received gabapentin. Exclusion criteria included contraindications for the operation based on severe cardiovascular diseases, nasal deformities (eg, known deformation of the nasal septum, visible distortion or deviation from the midline of the nasal septum), sleep apnea, hemorrhagic disease, or current therapeutic use of anticoagulants.

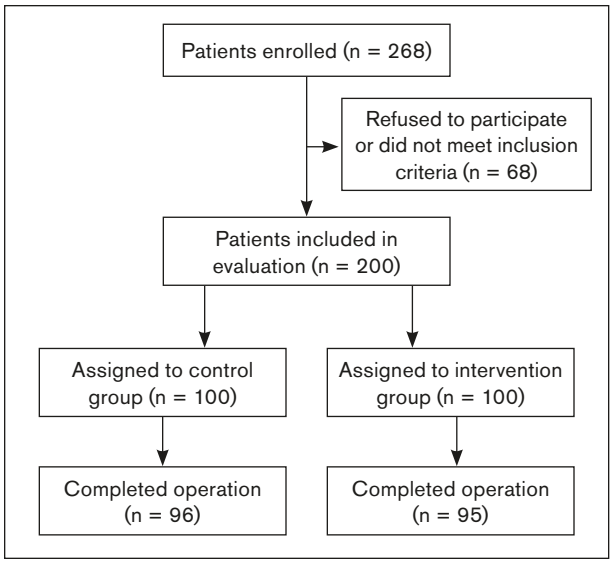

Fig 1 Flowchart showing assignment of 200 randomized patients to the intervention and control groups.

Randomization and Sequence Generation

A total of 268 patients were initially enrolled. However, 68 patients had to be excluded due to nasal deformities (n = 23), allergy to topical anesthetics (n = 2), treatment with anticoagulants (n = 13), and refusal to participate in the study (n = 30). Therefore, 200 patients were finally enrolled and randomly assigned by means of a computer-generated random allocation sequence into one of two groups: an intervention group in which NPA intubation was used (n = 100) or a control group in which an NPA intubation was not used (n = 100) (Fig 1).

Clinical Procedure

Sedation and Anesthesia. All patients were treated in the supine position. In the intervention group, the nostril was lubricated with a lidocaine gel to minimize the risk of damage to the nasal mucosa and to facilitate the tube insertion. A soft rubber tube (Argyle, 6.5-mm inner lumen, size 7 mm, length 115 mm; Covidien) was then inserted through the nostril and gently pushed along the nasal septum and the floor of the nasal cavity until the flanged end was flush against the posterior nasal opening. Usually, the insertion started on the contralateral side. If resistance was met, the attempt was stopped and the ipsilateral nostril was used. Digital subtraction angiography (Fig 2) was used to check that the tip of the tube was located above the

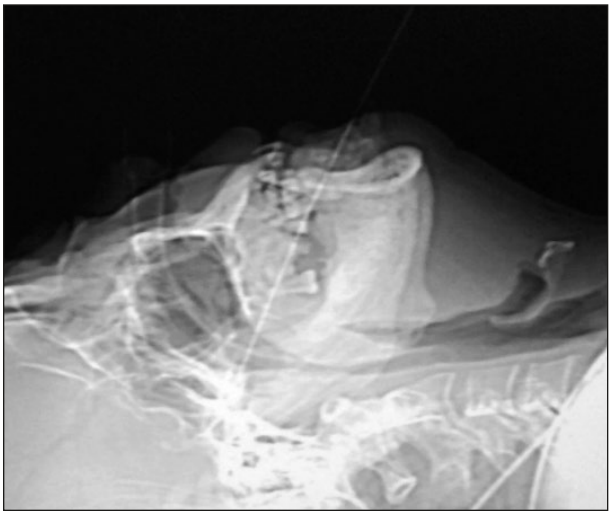

Fig 2 Radiographic image of the intubation tube and the thermocoagulation needle in one patient.

epiglottis. In the control group, patients were cured with oxygen through a face mask, but not NPA.

All patients received 3 L/minute of oxygen. Oxygen saturation (SaO_2), heart rate, and respiratory rate were monitored continuously after the patients reached the operation room. The patients' blood pressure was measured at 3-minute intervals during the procedure. Thereafter, all the patients received sufentanil (0.08 mg/kg). Once the needle was correctly positioned, propofol was administered (initial bolus dose: 1.0 mg/kg, then maintenance dose for continuous infusion: 4 mg/kg/hour) until the RFT was over. All sedations were performed by the same anesthesiologist.

Placement of the Thermocoagulation Needle. Computed tomography (CT) was used to determine the route of percutaneous insertion. The insertion point was marked on the skin of the cheek. After sterilization and local anesthesia with 0.5% lidocaine, a 20-G insulated needle (14.5 cm with a 5-mm active tip, Baylis Medical Company) was inserted and slowly advanced toward the foramen ovale along the designated path. When the depth of the needle reached the predefined depth, a new CT scan was performed to confirm the proper location of the needle tip. Thereafter, electrical stimulation was performed (sensory [50 Hz] and motor [2 Hz]) and the needle position adjusted until the stimulation elicited paresthesia in the affected area. After adequate analgesia and sedation were achieved, RFT was performed using the Pain Management Generator (PM-230, Baylis Medical Company) with the radiofrequency set at 75°C for 120 seconds in three cycles.[11] Thereafter, the patient was transferred to the recovery room. All procedures were performed by the last author, and the same RFT protocol was used for all patients in both groups.

Adverse Events

During RFT, an independent observer documented possible mucosal damage to the nose area and occurrence of hypoxia (SaO_2 < 90% detected by pulse oximetry) or hypotension (systolic blood pressure < 90 mm Hg). One day after the procedure, the same investigator checked and documented whether RFT complications such as corneal numbness, masticatory weakness, palsies of other cranial nerves, or intracranial hemorrhage had occurred. Corneal numbness was assessed by checking the corneal reflex. The presence of masticatory weakness was not quantified objectively, but was assessed subjectively by the patient.

Management of Respiratory Adverse Events. Several steps were taken in case of respiratory depression (SaO_2 < 90%): If the patient could breathe spontaneously, the oxygen flow was increased to improve oxygen supply. If the patient could not breathe spontaneously and SaO_2 continued to decline to less than 85%, assisted ventilation was performed. When the assisted ventilation also could not improve hypoxia, endotracheal intubation was performed to ensure the patient's safety.

Statistical Analyses

Sample Size. Respiratory depression events below 90% have been described in approximately 20% to 30% of cases during colonoscopy or interventional upper gastrointestinal tract endoscopy.[12,13] For sample size calculation, a 50% decrease in this frequency was considered as being clinically relevant. Based on this information, a sample size of at least 100 patients in each group was considered necessary to detect a significant difference with a power of 0.8, a type I error of 0.05, and a type II error of 0.2.

Data Analyses. Numeric variables were expressed as mean ± standard deviation (SD) or as the number of observations. Categorical variables were described using frequencies and percentages.

Differences in the frequencies of the adverse events between the two groups were assessed by using Fisher exact test. The statistical analyses were performed using the Statistical Package for Social Sciences version 19.0 (SPSS). A *P* value < .05 was considered to indicate statistical significance.

Results

Patient Demographics

In the control group, two patients dropped out because of angina pectoris attacks in the operation room, one because of dyspnea, and one due to failure of the procedure. In the intervention group, one patient dropped out because of dyspnea, two

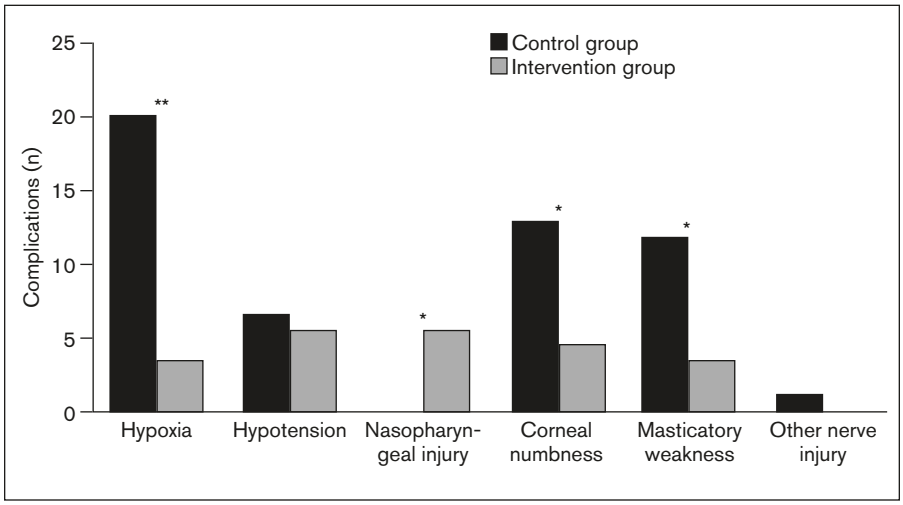

Fig 3 Frequency of complications in the two groups. *P < .05. **P < .001.

Table 1 Baseline Characteristics of the Participants (Mean ± Standard Deviation [SD])

Patients	Control group (n = 100; completed = 96)	Intervention group (n = 100; completed = 95)	P
Age (y)	62.03 ± 12.69 (61.96 ± 12.66)	65.11 ± 11.85 (65.14 ± 11.81)	.627
Female/male (n)	53/47 (52/44)	55/45 (52/43)	.778
Weight (kg)	66.96 ± 9.66 (66.99 ± 9.62)	66.65 ± 10.43 (66.60 ± 10.47)	.832
2nd branch TN/3rd branch TN/both (n)	29/56/15 (28/54/14)	31/53/16 (30/50/15)	.915
Propofol dose (mg)	156.60 ± 24.50 (156.41 ± 24.59)	155.65 ± 24.57 (155.52 ± 24.63)	.787
Sufentanil dose (mg)	5.42 ± 0.50 (5.45 ± 0.53)	5.46 ± 0.52 (5.43 ± 0.54)	.537

TN = trigeminal nerve.

because of a hypertension crisis, and two because they did not tolerate the insertion of the tube through the nose. Thus, the intervention and control groups had 96 and 95 patients, respectively (Fig 1).

The two groups did not differ for age, gender, weight, the branch of the trigeminal nerve affected, or doses of propofol and sufentanil used (P > .05) (Table 1).

Adverse Effects of NPA Intubation

NPA intubation was successful in all patients. In 22 patients, the tube had to be inserted through the ipsilateral nostril because some resistance was encountered when it was inserted through the contralateral nostril. None of the procedures were cancelled due to a sedation-related event. Reversible episodes of respiratory depression (SaO_2 < 90%) and several secondary outcomes, such as corneal numbness and masticatory weakness, occurred significantly less frequently in the intervention group than in the control group (P < .05) (Fig 3). RFT complications were examined 1 day after the radiofrequency operation. Five patients (5%) experienced a nasopharyngeal injury—one had nose bleeding, and the tube was tinged with blood in the other four. In all these cases, bleeding stopped spontaneously within 10 minutes after tube removal, and none of the five patients required any further therapy. No significant difference was observed in the incidence of systolic blood pressure < 90 mm Hg in the two groups (P > .05).

Discussion

Classical trigeminal neuralgia is the most common form of craniofacial neuralgia. RFT of the trigeminal ganglion is a useful therapy that must be performed under sedation for both pain relief and anxiety control.[2,14] The use of propofol has significantly increased in past years due to its pharmacologic benefits; ie, its rapid onset and short duration of action.[15–17] However, propofol anesthesia may lead to a severe complication, transient apnea, especially when used in combination with opioids.[18] Propofol can induce and maintain all levels of sedation, ranging from moderate sedation to general anesthesia, depending on the dose.[19] There is, however, a great variability in patient responses: in some patients, even a small dose may induce deep sedation or even anesthesia.[20]

With NPA intubation, the incidence of upper airway obstruction was significantly reduced; hence, the rate of oxygen desaturation was significantly lower in the intervention group than in the control group (P < .05). In the control group, 19% of the patients

experienced oxygen desaturation, which is higher than what has been reported (13%) by Muller et al.[21] However, in this study patients were laying in a supine position, which could explain this difference in findings, as it is possible that the risk of glossoptosis is higher when the patient is in a supine rather than a lateral position.

Another common complication of propofol is dose-dependent hypotension. In the present study, no significant difference in the frequency of hypotension was found between the two groups. The frequency (5.5%) of patients with a hypotensive episode (systolic blood pressure < 90 mm Hg) recorded in this study was lower than that recorded in patients undergoing endoscopic sedation.[22]

RFT of the trigeminal ganglion can lead to serious complications, such as masticatory weakness, paralysis, and corneal numbness, with frequencies of 14.8%, 2.2%, and 9.6%, (range 3% to 20%), respectively.[2,11,23,24] In the present study, the frequencies of masticatory weakness and corneal numbness in the control group were in accordance with those reported in previous studies, and these complications occurred significantly less often in the intervention group. It is possible that this was due to the fact that the flexible tube used for the NPA intubation kept the airway open, thus reducing the risk of upper airway obstruction and the necessity of lifting the patient's jaw for assisted ventilation, a maneuver that could possibly have displaced the position of the thermocoagulation needle tip. However, no CT had been performed in the patients of the control group to check whether the jaw manipulation had actually displaced the needle tip.

Another very low-risk complication of RFT is cranial nerve deficits that, according to a large case series of 1,600 patients, occurred in 0.8% of cases (transient palsy of the third cranial nerve in 1 patient and of the sixth cranial nerve in 11 patients, as well as permanent palsy of the sixth cranial nerve in 2 patients[2]). In this study, only one patient had a transient palsy of the sixth cranial nerve on the first day after thermocoagulation therapy, which fully recovered after 2 weeks of neurotrophic treatment (intramuscular injection of ganglioside, 40 mg per day).

It can be assumed that complications such as nasal mucosal injury with possible aspiration of the blood, risk of retropharyngeal perforation, and additional costs have limited the clinical application of NPA intubation.[9] The most common complication of this procedure is damage of the nasal mucosa.[25,26] Therefore, a special flexible, thin, and properly lubricated tube was used to avoid mucosal injury in the present study. Only 5% of patients experienced mucosal injuries, which resolved spontaneously in all of them. This low rate might be due to the exclusion of patients taking anticoagulation therapy and of those with nasal deformities.

This study had some limitations. First, being a pilot study, it was performed at only a single center. Further investigations in other centers are therefore necessary to validate these findings. Second, it was difficult to recruit a larger number of patients because 25.4% of all eligible patients refused to participate due to their unwillingness to undergo NPA intubation, which may have led to selection bias.

Conclusions

NPA intubation by means of a thin and flexible tube was found to reduce the frequency of sedation-related adverse events and the incidence of complications related to RFT of the trigeminal ganglion. These findings provide support for the clinical application of NPA intubation in the treatment of classical trigeminal neuralgia.

Acknowledgments

The research was supported by a Grant-In-Aid award (No: 30840075) from the National Natural Science Foundation of China and Liaoning Education Committee Scientific Research Funding (No: L2012283) (to TS) (Clinical Trial Registration: NO ChiCTR-IPR-15005754). The authors report no conflicts of interest.

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