## DECLARATION OF ROGER LOPEZ

I, Roger Lopez, pursuant to 28 U.S.C. § 1746 and 37 C.F.R. § 1.68, hereby declare as follows:

1. I am a Translator for Morningside Translations.

2. I submit this declaration to certify the accuracy of the English translation of Liang et al., *Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy*, 13:8 J. Clin. Otorhinolaryngology (China) 341 (Aug. 1999).

3. I am qualified to perform Chinese to English translations and certify the accuracy of Chinese to English translations.

4. My statements are based on personal knowledge and my review of Liang et al., *Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy*, 13:8 J. Clin. Otorhinolaryngology (China) 341 (Aug. 1999) and its Chinese to English translation. If called as a witness about the facts contained in these statements, I could testify competently based on such personal knowledge and the investigation I have conducted.

5. Attached as **Exhibit A** is a true and accurate copy of Liang et al., *Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy*, 13:8 J. Clin. Otorhinolaryngology (China) 341 (Aug. 1999).

6. Attached as **Exhibit B** is a true and accurate copy of an English translation of Liang et al., *Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy*, 13:8 J. Clin. Otorhinolaryngology (China) 341 (Aug. 1999) (hereinafter, "Liang Translation"), which I prepared based on Exhibit A and my personal knowledge of the Chinese and English languages.



NEURENT 1072

7. Liang Translation is a true and accurate translation of Liang et al., *Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy*, 13:8 J. Clin. Otorhinolaryngology (China) 341 (Aug. 1999) from Chinese to English.

8. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true.

9. I have been warned and am aware that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001.

10. I understand that by submitting this declaration I may be asked to appear for a deposition asking me questions limited to the material in my declaration. With my signature below, I agree to make reasonable efforts to make myself available for such a deposition at a reasonable place and time.

* * *

I declare under the penalty of perjury that the foregoing is true and correct. Executed on 20/12/2023 in Missouri.

Roger Lopez

Roger Lopez

# Exhibit A

# 鼻内窥镜射频热凝筛前神经治疗变应性鼻炎*

梁建平[1] 尹曼莉[1] 李东云[1] 陈世强[1] 侯萍[1] 陈慧[1] 袁弘[1]

**摘要** **目的**:探讨提高治疗变应性鼻炎效果的方法。**方法**:利用鼻内窥镜下筛前神经射频治疗变应性鼻炎患者 88 例,随防 1 年。**结果**:显效 73 例(83.0%),有效 11 例(12.5%),无效 4 例(4.5%),总有效率达95.5%。**结论**:鼻内窥镜下筛前神经射频治疗变应性鼻炎具有疗效显著、操作方便、治疗部位准确等优点,有较好临床应用价值。

**关键词** 变应性鼻炎 筛前神经 鼻内窥镜 电凝法

## Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy

*Liang Jianping Yun Manli Li Dongyun et al*

(Department of Otolaryngology, the People's Hospital of Guangxi Autonomus Region, Nanning 530021)

**Abstract** **Objective**: To study the effect of radiofrequency treatment of ethmoidal nerve on allergic rhinitis. **Method**: Eighty-eight cases of allergic rhinitis were treated with ethmoidal nerve radiofrequency under nasal endoscopy. **Result**: It showed marked effectiveness in 73 cases (83.0%), immprovement in 11 cases (12.5%) and failed in 4 cases (4.5%) in one year follow-up. The overall effective rate was 95.5%. **Conclusion**: This result indicated that it is a choice for treating allergic rhinitis to apply ethmoidal nerve radiofrequency under nasal endoscopy.

**Key words** Allergic rhinitis Ethmoidal nerve Nasal endoscopy Electrocoagulation

鼻腔副交感神经活动性增高是变应性鼻炎发病的一种重要因素。1996 年 10 月～1997 年 9 月,我们应用射频热疗仪于鼻内窥镜下,热凝筛前神经治疗变应性鼻炎 88 例,经随访 1 年疗效显著。现报告如下。

## 1 资料与方法

### 1.1 临床资料

88 例患者均符合 1997 年海口会议修订的"变应性鼻炎诊断标准及疗效评定标准"。其中男 49 例,女 39 例;年龄 14～69 岁,平均35.5岁。病程为 1～30 年。均在本治疗前应用过抗组胺药物和激素类药物等治疗,但疗效不明显。

### 1.2 治疗方法

患者取平卧位或半卧位,用 2%地卡因肾上腺素棉片行鼻腔粘膜麻醉,着重于中鼻甲前方(鼻丘)和与其相对应的鼻中隔部位。然后应用 SHP-Ⅰ型五官科射频治疗仪(广州医疗器械厂产),负极接患者颏下部,强度为 3 档。在鼻内窥镜直视下用发射头对双侧鼻丘和与之相对应的鼻中隔粘膜进行热凝治疗。热凝范围约 1 cm×1 cm,鼻丘处时间为 5 s,鼻中隔侧为 3 s,以局部粘膜变白斑为宜。治疗后给予 1%麻黄素滴鼻,减轻粘膜反应性肿胀,及时清理鼻腔反应膜。治疗后观察期间不用抗组胺和激素类药物,以免干扰疗效观察。于治疗后半年、1 年进行随访复查,复查内容包括鼻部自觉症状改善情况和鼻腔检查所见。全部患者均只进行 1 次热凝治疗。

## 2 结果

全组患者治疗后均随访 1 年以上。根据 1997 年海口会议修订的疗效评定标准,88 例中,显效 73 例(83.0%),有效 11 例(12.5%),无效 4 例(4.5%),总有效率为95.5%。患者在接受治疗后 3～5 d,可因鼻腔反应而出现鼻塞、流涕或少量血性分泌物等症状,1 周后逐渐好转。本组 2 例于治疗后半年复发,5 例出现鼻腔粘连经处理后好转;无鼻中隔穿孔、鼻干燥、嗅觉减退等并发症发生。

## 3 讨论

变应性鼻炎的发病除了抗原、抗体反应外,与植物神经系统有关。筛前神经鼻内支主要分布于鼻丘和与之相对应的鼻中隔粘膜。利用鼻内窥镜直视下观察鼻内结构,可不受鼻腔解剖异常的影响,方便操作,克服了普通鼻窥的缺点,能准确选择治疗部位,提高疗效。本组患者有效率达95.5%,明显优于我们此前应用普通鼻窥筛前神经电离子烧灼的疗效(有效率84.7%)。

射频主要是利用射频电磁波使局部细胞产生强烈的内生热效应,引起蛋白热凝固,血管闭塞,组织变性、萎缩而治疗疾病。射频治疗不但可使鼻丘和与之相对应鼻中隔处敏感的粘膜变性萎缩,腺体

*本课题为广西留学回国人员科学基金资助项目

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破坏，还可使其深部的筛前神经受到不同程度的破坏，而致其对外界的物理、化学不良刺激敏感性降低，减少血管活性肽的分泌，抑制喷嚏反射，减少流涕，改善鼻腔通气，从而达到治疗变应性鼻炎的目的[1,2]。

射频治疗的强度选择，对疗效和预防并发症有较大的影响，强度小，治疗时间短，不能有效地破坏局部粘膜神经；而强度大，治疗时间长则有可能对深层组织造成损伤，特别是鼻中隔侧的治疗。我们认为强度选择在 3 档，鼻丘处粘膜较厚，时间可长些(5 s)，鼻中隔处时间短些(3 s)，且两侧尽可能错开，以免造成鼻中隔穿孔。本组患者无鼻中隔穿孔发生。治疗后及时清理鼻腔反应膜，是预防鼻腔粘连的关键，本组有 5 例患者发生鼻腔治疗部位粘连，经处理后好转。

本组 2 例于治疗后半年出现复发，但症状体征仍较本治疗前轻。此 2 例均有明显的鼻中隔偏曲。考虑可能是治疗中因鼻中隔偏曲限制了凸出侧的射频治疗范围，影响了疗效。后另行鼻中隔矫正术，变应性鼻炎的症状明显减轻；另外，筛前神经的分布异常也可能是影响疗效或导致复发的原因之一。我们体会，本疗法视野清晰，直观，无明显副作用和严重并发症，疗效明显，具有较好的临床应用价值。

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(收稿 1999-01-12)

(编辑 周作新)

# 鼻内窥镜下微波热凝治疗婴儿鼻咽部畸胎瘤 1 例

樊亚琴[1]　董明福[1]　胡红容[1]

畸胎瘤发生在鼻咽部者极少见。我科曾收治 1 例，经鼻内窥镜下微波热凝治疗，效果良好。报道如下。

患者，女，9 月。2 月前其母发现患儿夜间睡眠时打鼾，逐渐加重，吃奶时常发生呛咳、憋气致喂养困难，加重 2 d 于 1998 年 6 月 29 日入院。体检：体重 6 kg，营养差，全身系统检查无异常。专科检查：外鼻无畸形，左鼻腔正常。左侧软腭后方见一灰白色肿物坠于口咽部，约 4 cm×2 cm 大小，阻塞口咽部约 4/5。瘤体表面光滑，实性质韧，活动，不易出血，蒂在鼻咽左侧壁。CT 示鼻咽部左侧有一 3 cm×2 cm 肿块，根蒂位于咽鼓管圆枕后，基底宽约 0.5 cm。术前未取活检。诊为：鼻咽部肿瘤(性质待定)。

手术于 1998 年 7 月 6 日在全麻气管插管下进行。选用 0°，70°鼻内窥镜(美国 Stryker 公司产)，(D＝4 mm) MTC-4 型多功能微波手术治疗仪(南京启亚科技有限公司产)。患者取仰卧位，开口器固定口腔。0°鼻内窥镜经左鼻腔放入至鼻咽部查明肿瘤范围，基底部位与周围的关系。同时经口腔轻牵软腭将瘤体牵住。电视监视下见瘤体完全阻塞左侧后鼻孔，稍向口腔牵拉后，暴露后鼻孔。经后鼻孔视清瘤体蒂位于左侧咽鼓管圆枕后方，基底宽约 0.5 cm。先用注射器穿刺抽吸证实无液体后，将盐水纱条置于咽鼓管口周围，保护咽鼓管开口。选用双针微波探头(功率 45 W，时限 1～5 s)，脚踏开关控制。在鼻内窥镜电视监视下，将微波探头经口腔放入瘤体根部与咽鼓管圆枕之间，启动微波凝固瘤体基部，反复 3 次，每次 2 s，瞬间见瘤体基部变白(总时间 6 s)，即停止微波输入。将瘤体从口腔轻轻拉出，基底部渗血约 5 ml，再次微波凝固瘤体基底部至其表面变白，无活动性出血，取出咽鼓管周围盐水纱条，创面不予填塞，术毕。瘤体大 4 cm×2 cm，表面有纤细茸毛，剖开后，中央为脂肪组织，未见液体及软骨。病理报告：鼻咽部良性畸胎瘤。

术后 6 h 开始进食牛奶。术后局部反应轻微。创面始终无出血，每日予抗生素滴鼻剂滴鼻 4 次，7 d 出院。

**讨论**　畸胎瘤是一种先天性肿瘤，多为良性，一般出生时就有，但以小儿，特别是新生儿、婴儿为常见。常为无痛性肿块。如肿瘤较大或生长在易引起压迫或阻塞症状的部位，则较早出现症状，本例即由鼻咽坠入口腔引起吞咽呛咳而发现。

对于咽部及鼻咽顶有细蒂之肿瘤，手术切除要简单些，但对位于鼻咽深部、蒂根较宽的肿瘤，盲目手术易残留、复发。鼻内窥镜下手术光线明亮，可视清鼻咽各个部位，操作简便，手术安全、彻底。

微波组织热凝术中，探头接触瘤体后，加热部位界限清楚，止血良好，无碳化。可选择不同型号、可弯曲的微波探头，深入到鼻咽各个部位，使手术更彻底，即使微波探头被血痂包裹，仍不影响其持续的热凝效应。应该注意的是，术中要用盐水纱条保护咽鼓管口。

(收稿 1998-11-05)

(编辑 周作新)

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# Exhibit B

# Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy *

Liang Jianping[1], Yin Manli[1], Li Dongyun[1], Chen Shiqiang[1], Hou Ping[1], Chen Hui[1], Yuan Hong[1]

**Abstract Objective:** To study the effect of radiofrequency treatment of ethmoidal nerve on allergic rhinitis. **Method:** Eighty-eight cases of allergic rhinitis were treated with ethmoidal nerve radiofrequency under nasal endoscopy. **Result:** It showed marked effectiveness in 73 cases (83.0%), improvement in 11 cases (12.5%), and failure in 4 cases (4.5%) in one-year follow-up. The overall effective rate was 95.5%. **Conclusion:** Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy has such advantages as significant therapeutic effect, convenient operation, and accurate treatment site, and has good clinical application values.

**Key words** Allergic rhinitis Ethmoidal nerve Nasal endoscopy Electrocoagulation

## Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy

*Liang Jianping Yun Manli Li Dongyun et al*

(Department of Otolaryngology, the People's Hospital of Guangxi Autonomus Region, Nanning 530021)

**Abstract Objective:** To study the effect of radiofrequency treatment of ethmoidal nerve on allergic rhinitis. **Method:** Eighty-eight cases of allergic rhinitis were treated with ethmoidal nerve radiofrequency under nasal endoscopy. **Result:** It showed marked effectiveness in 73 cases (83.0%), immprovement in 11 cases (12.5%) and failed in 4 cases (4.5%) in one year follow-up. The overall effective rate was 95.5%. **Conclusion:** This result indicated that it is a choice for treating allergic rhinitis to apply ethmoidal nerve radiofrequency under nasal endoscopy.

**Key words** Allergic rhinitis Ethmoidal nerve Nasal endoscopy Electrocoagulation

The increased activity of the parasympathetic nervous system in the nasal cavity is an important factor in the onset of allergic rhinitis. From October 1996 to September 1997, we used radiofrequency hyperthermia devices under nasal endoscopy to treat 88 cases of ethmoidal nerve with allergic rhinitis by thermocoagulation. After 1 year of follow-up, the therapeutic effect was significant. Now a report is given as follows.

**1 Data and Methods**

**1.1** Clinical data

All the 88 patients complied with the "Diagnostic Criteria and Efficacy Evaluation Criteria for Allergic Rhinitis" revised at the 1997 Haikou Conference. Among the patients, there were 49 males and 39 females aged at 14-69 years old with an average age of 35.5 years. The course of disease ranged from 1 to 30 years. All the patients were treated with antihistamines and hormone drugs before this treatment, but the efficacy was not significant.

**1.2** Treatment methods

The patient was put in the supine or semi-reclining position and was subjected to nasal mucosal anesthesia using a 2% dicaine epinephrine sponge, focusing on the anterior part of the middle turbinate (nasal ridge) and its corresponding nasal septum. Then, the SHP-I radiofrequency treatment device for facial organs (manufactured by Guangzhou Medical Device Factory) was used, with the negative electrode connected to the lower part of the patient's chin and an intensity of Level 3. Under direct nasal endoscopy, the emitter was used to perform thermal coagulation treatment on the bilateral nasal ridge and the corresponding nasal septum mucosa. The range of thermal coagulation was about 1 cm x 1 cm, with a treatment duration of 5 seconds for the nasal ridge and 3 seconds for the septal side of the nose, preferably to have white spots of local mucosa. After treatment, 1% ephedrine nasal drops was given to reduce reactive swelling of the mucosa and the nasal reactive membrane was promptly cleaned. During the observation period after treatment, antihistamines and hormone drugs were not used, so as to avoid interfering with the efficacy observation. Follow-up examinations were carried out at half a year and one year after treatment, including the improvement of nasal symptoms and findings from nasal examinations. All the patients underwent only one thermal coagulation treatment.

**2 Results**

After treatment, all the patients in the study were followed up for more than 1 year. According to the efficacy evaluation criteria revised at the 1997 Haikou Conference, among the 88 cases, it showed marked effectiveness in 73 cases (83.0%), improvement in 11 cases (12.5%), and failure in 4 cases (4.5%), and the overall effective rate was 95.5%. 3-5 days after treatment, the patients might experience symptoms such as nasal congestion, runny nose, or a small amount of bloody secretions due to nasal reactions, which were gradually improved after 1 week. In the study, 2 patients had recurrence at six months after treatment, and 5 patients developed nasal adhesion which was improved after treatment; No complications such as nasal septum perforation, nasal dryness, or decreased olfactory function occurred.

**3 Discussions**

The onset of allergic rhinitis is not only associated with antigen and antibody reactions, but also with the autonomic nervous system. The internal branch of the ethmoidal nerve is mainly distributed on the nasal ridge and the corresponding nasal septum mucosa. By using a nasal endoscope to observe the nasal structure directly, it is not affected by abnormal nasal anatomy, it is convenient to operate, the disadvantages of ordinary nasal endoscopy can be overcome, the treatment site can be accurately selected, and the therapeutic effect can be improved. The effective rate for the patients in this study reached 95.5%, which was significantly higher than that of our previous use of conventional endoscope for ethmoidal nerve electrocautery (with an effective rate of 84.7%).

For radiofrequency, radiofrequency electromagnetic waves are mainly used to generate strong endogenous heat effects in local cells, causing thermal coagulation of protein, vascular occlusion, tissue degeneration, and atrophy to treat diseases. Radiofrequency treatment can not only cause degeneration and atrophy of the sensitive mucosa on the nasal ridge and corresponding nasal septum, as well as

* This project was supported by Guangxi Science Foundation for Returned Overseas Students

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damage to the glands, but also can cause varying degrees of damage to the deep ethmoidal nerve, reducing its sensitivity to adverse external physical and chemical stimuli, reducing the secretion of vasoactive peptides, inhibiting sneezing reflex, reducing runny nose, and improving nasal ventilation, thus achieving the goal of treating allergic rhinitis [1, 2].

The intensity selection of radiofrequency treatment has a significant impact on the efficacy and prevention of complications. When the intensity is low and the treatment duration is short, it cannot effectively damage the local mucosal nerves; however, when the intensity is high and the treatment duration is long, it may cause damage to the deep tissues, especially in the treatment of the nasal septum. In our opinion, the intensity should be selected at Level 3, and as the mucosa at the nasal ridge is thick, the duration can be long (5 seconds), and the duration at the nasal septum can be short (3 seconds), and both sides should be staggered as much as possible to avoid perforation of the nasal septum. There were no cases of nasal septum perforation in the patients in this study. The key to preventing nasal adhesion is to timely clean the nasal reaction membrane after treatment, and in this study, 5 patients experienced nasal adhesion at the treatment site, which was improved after treatment.

In this study, 2 patients experienced recurrence at half a year after treatment, but the symptoms and signs were still milder than those before this treatment. The two patients had obvious deviation of the nasal septum. It was possible that the deviation of the nasal septum during treatment limited the range of radiofrequency treatment on the protruding side, which affected the therapeutic effect. After undergoing nasal septum correction surgery, the symptoms of allergic rhinitis were significantly relieved; in addition, abnormal distribution of the ethmoidal nerve might also be one of the reasons that affected the treatment efficacy or led to recurrence. According to our experience, this treatment has a clear and intuitive field of vision, has no obvious side effects or serious complications, has significant therapeutic effects, and has good clinical application values.

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(Received on January 12, 1999)
(Edited by Zhou Zuoxin)

## Treatment of infantile nasopharyngeal teratoma with microwave thermocoagulation under nasal endoscopy: Report of one case

Fan Yaqin[1], Dong Mingfu[1], Hu Hongrong[1]

Teratoma occurring in the nasopharynx is extremely rare. One patient was admitted to our department and treated with microwave thermal coagulation under nasal endoscopy, with good results. Now a report is given as follows.

The patient was a 9-year-old female. Two months ago, her mother found that the child snored during nighttime sleep, which was gradually worsened. She often choked and held her breath while breastfed, causing breastfeeding difficulties. The condition was worsened for two days and she was admitted to the hospital on June 29, 1998. Physical examination: The patient had a body weight of 6 kg, with poor nutrition, and with no abnormalities found in the systemic examination. Specialized examination: There was no abnormality of the external nose, and the left nasal cavity was normal. A grayish white mass, approximately 4 cm x 2 cm in size, was found behind the left soft palate, obstructing approximately 4/5 of the oropharynx. The surface of the tumor was smooth, the parenchyma was stiff, active, and not easy to bleed. The pedicle was on the left wall of the nasopharynx. CT showed a 3 cm x 2 cm mass on the left side of the nasopharynx, with the root located behind the occipital part of the eustachian tube and with a basal width of approximately 0.5 cm. No biopsy was carried out before the surgery. Diagnosis: Nasopharyngeal tumor (nature to be determined).

The surgery was performed on July 6, 1998 under general anesthesia and tracheal intubation. One 0° and 70° nasal endoscope (manufactured by Stryker in the United States) and one (D=4 mm) $MTC^{-4}$ multifunctional microwave surgical treatment device (manufactured by Nanjing Qiya Technology Co., Ltd.) were used. The patient was put in the supine position and the mouth was fixed with a mouth opener. The 0° nasal endoscope was put through the left nasal cavity into the nasopharynx to determine the range of the tumor and the relationship between the base and the surrounding area. At the same time, the soft palate was gently pulled through the oral cavity to hold the tumor. Under TV stakeout, it was found that the tumor completely blocked the left posterior nostril, and then it was slightly pulled toward the oral cavity and exposed. The pedicle of the tumor was found as observed via the posterior nostril to be located behind the occipital part of the left eustachian tube, with a base width of approximately 0.5 cm. Firstly, a syringe was used to puncture and aspirate to confirm the absence of liquid, then a saline gauze strip was placed around the opening of the eustachian tube to protect it. A dual pin microwave probe (with a power of 45 W and a time limit of 1-5 s), controlled by a pedal switch, was used. Under the stakeout of nasal endoscope, the microwave probe was placed via the oral cavity between the root of the tumor and the occipital part of the eustachian tube, and microwaves were initiated for coagulation of the tumor base. This process was repeated for 3 times, with each time lasting for 2 seconds, and instantly the base of the tumor turned white (for a total time of 6 seconds), and then the microwave input was stopped. The tumor was gently pulled out from the oral cavity, with about 5 ml of blood oozed from the base. The base of the tumor was coagulated again using microwaves until its surface turned white without active bleeding. The saline gauze around the eustachian tube was removed, without filling the wound, and the surgery was completed. The tumor was 4 cm x 2 cm in size, with fine hairs on the surface. After dissection, the center was composed of adipose tissues, and no fluid or cartilage was found. Pathological report: Benign teratoma of the nasopharynx.

Milk was fed at 6 hours after the surgery. The postoperative local reactions were mild. The wound still had no bleeding, and antibiotic nasal drops were administered four times a day. The patient was discharged at 7 days later.

**Discussion** Teratoma is a congenital tumor, mostly benign and usually present at birth, but it is more common in children, especially newborns and infants. It is usually a painless lump. If the tumor is large or grows in a location that is prone to causing compression or obstruction symptoms, the symptoms occur early. In this patient, it was discovered by swallowing and coughing when it fell from the nasopharynx into the mouth.

For tumors with fine pedicle in the pharynx and nasopharynx top, surgical resection is simpler. However, for tumors located in the deep part of the nasopharynx and with a wide pedicle, surgery with no stakeout is prone to causing residue and recurrence. Under nasal endoscopy, the surgical light is bright, and the various parts of the nasopharynx can be seen clearly, and the operation is simple, safe, and thorough.

In microwave tissue thermocoagulation, when the probe is in contact with the tumor, the boundary of the heated site is clear, the hemostasis is good, and there is no carbonization. Different models and bendable microwave probes can be selected to put into various parts of the nasopharynx, making the surgery more thorough. Even if the microwave probe is wrapped with blood scabs, its sustained thermal coagulation effect is still not affected. It should be noted that saline gauze should be used during the surgery to protect the opening of the eustachian tube.

(Received on November 5, 1998)
(Edited by Zhou Zuoxin)

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