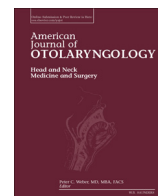




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Comparison of the effects of esomeprazole plus mosapride citrate and botulinum toxin A on vocal process granuloma

Lei Lei, Hui Yang^{*}, Xinsheng Zhang¹, Jia Ren

Department of Otorhinolaryngology, Head & Neck Surgery, West China Hospital, West China Medical School, Sichuan University, Chengdu, Sichuan, China

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ABSTRACT

Objectives: Vocal process granulomas have a high tendency for persistence despite many treatment alternatives. Anti-reflux medications or botulinum toxin A injections are the main current therapies. There are no studies that compare the effects on vocal process granuloma of proton pump inhibitors plus prokinetic agents with botulinum toxin A injections.

Study design: Prospective cohort study.

Methods: Adult patients reporting to our outpatient department complaining of trachyphonia and/or abnormal pharyngeal sensations who were found to have contact granulomas. Patients were divided into two groups according to the treatment: esomeprazole with mosapride citrate ($n = 26$) or botulinum toxin A injection ($n = 20$). The reflux symptom index and reflux finding score determined by electronic fibrolaryngoscopy were utilized to assess efficacy.

Results: Forty-six patients were recruited (43 male; 3 female). The mean age (range) was 48.3 years (38–69) and the body mass index was 23.51 kg/m^2 (19.13 – 27.89). Laryngopharyngeal reflux disease diagnosed by RSI or RFS was found in 18 and 27 patients, respectively, and 18 diagnosed without laryngopharyngeal reflux disease. Twenty patients (95%) were cured in the esomeprazole with mosapride citrate group and nine (45%) in the botulinum toxin A group. Eleven (55%) patients had recurrence after botulinum toxin A injection, with an average interval of 3.1 months (range 1–6). The recorded symptoms after therapy resolved within 6 months with a statistically significant improvement in the esomeprazole with mosapride citrate group.

Conclusions: Combined proton pump inhibitor plus prokinetic drug therapy plays a significant role in the treatment of vocal process granulomas or after surgery.

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1. Introduction

Contact granulomas are uncommon disorders arising from the vocal process of arytenoid cartilage, and less commonly from its body. Therefore, they are also called arytenoid granuloma or vocal process granulomas (VPGs). VPGs have various etiology, such as laryngopharyngeal reflux (LPR), intubation, vocal abuse, habitual throat clearing [1].

VPGs have a high tendency for persistence despite many treatment alternatives. They also has high tendency for spontaneous disappearance without treatment but can also recur easily when removed surgically [2,3].

Patients with VPGs have been given botulinum toxin A injections as initial treatment in many articles, with reported resolution rates up to

100% [4,5]. However only Damrose et al. [4] contained a cohort of patients treated solely with such injection. On the other hand, when anti-reflux treatment is targeted specifically toward proven LPRD, it is clear that the efficacy of treatment increases for VPGs, because LPRD is believed to be an important contributory factor [2,6].

Treatment with proton pump inhibitors (PPIs) can significantly improve reflux symptoms in patients with LPRD and have been described in recent studies [7]. However, increasing research has shown weak effects of PPI used only for treating laryngeal granuloma than with other treatments or a placebo [8]. The efficacy of PPIs plus prokinetic drugs for the treatment of laryngopharyngeal reflux is better than with PPIs or prokinetic drugs by themselves [9,10]. In our clinical works, we also found that botulinum toxin A injections had less effect than esomeprazole plus mosapride in patients with VPGs with or without LPRD.

The aim of this study was to compare the effects of esomeprazole plus mosapride citrate with those of botulinum toxin A injection, on VPGs. To our knowledge, this study was the first time to compare the treatment results of esomeprazole plus mosapride citrate with botulinum toxin A injection.

^{*} Corresponding author at: Department of Otorhinolaryngology, Head&Neck Surgery, West China Hospital, West China Medical School, Sichuan University, 37 Guoxuexiang, Wuhou District, Chengdu, Sichuan, China.

E-mail address: yh8806@163.com (H. Yang).

¹ Contributed equally as first author.

2. Materials and methods

The study was conducted in West China Hospital of Sichuan University, and every patient gave a written informed consent before any study-related procedures were performed.

2.1. Patients

Adult patients aged 18 years or older who presented to our outpatient department complaining of trachyphonia (hoarseness) and/or abnormal pharyngeal sensations, and who were diagnosed with laryngeal granulomas by electronic fibrolaryngoscopy, were recruited for this study. Exclusion criteria were as follows: known allergies for esomeprazole or any other PPI; disease of the immune system; deformities and tumors of pharynx and larynx; or failure to comply with the prescribed medication. All patients were asked to stop smoking, drinking, and avoid eating for 2–3 h before sleeping, and to avoid voice abuse from when they began to receive treatment.

2.2. Measures

Measures of the reflux symptoms index (RSI) [11] and reflux founding score (RFS) [12] by electronic fibrolaryngoscopy were taken before the patients received treatment. Patients were divided into two groups according to the treatment requested. The group receiving esomeprazole with mosapride citrate ($n = 26$) were treated with esomeprazole (20 mg) twice daily and mosapride citrate (5 mg) triple daily for 6 months and were instructed to use them as needed. On the other hand, in the group receiving botulinum toxin A ($n = 20$), patients were treated with botulinum toxin A injection at four points through thyrohyoid membrane to bilateral thyroarytenoid and lateral cricoarytenoid muscles at 2×1.25 U to 2×2.5 U, only as an daytime operation procedure. In the two groups, no voice therapy was applied.

There were follow-up visits after 1, 2, 3 and 6-month, during which the same procedures were repeated. Any VPGs that had disappeared were recorded as cured. If lesions persisted or a recurred, this lack of efficacy were recorded as treatment failure, even when some symptoms or other signs had disappeared. During the follow-up visits, assessment of laryngopharyngeal signs by electronic fibrolaryngoscopy was always performed. Main symptoms (trachyphonia, clearing the throat, nagging cough and abnormal pharyngeal sensations) were measured using the RSI according to the guidelines defined by Belafsky [11].

The results are given as means and chi-square test, with 95% confidence interval for variables with normal for variables with non normal distributions. P values ≤ 0.05 were considered statistically significant. Statistical analyses were performed with SPSS version 18.0.

3. Results

Forty-six patients were recruited (43 male and 3 female). Their mean (range) age was 48.3(38–69) years and body mass index (BMI) was 23.51 Kg/m² (19.13–27.89). LPRD diagnosed by RSI and RFS was found in 18 and 27, and 18 were diagnosed without laryngopharyngeal reflux disease. They were divided into two groups according to their treatment request: 20 in the botulinum toxin A group and 26 in the esomeprazole plus mosapride citrate group and 11 of them were patients with treatment failure from the botulinum toxin A group. There were no significant associations between age, gender, fatty diet intake, course, current smoking, drinking habits, BMI, RSI or RFS values between the two groups of patients (Table 1).

Twenty patients (96%) were cured in the esomeprazole plus mosapride citrate group and nine (45%) in the botulinum toxin A group (Fig. 1). One patients presented with a persistent VPGs after eight anti-reflux treatments using esomeprazole with mosapride citrate and was recorded as a treatment failure. Eleven (55%) patients had a recurrent VPGs after botulinum toxin A injection at 1 to 6-month follow

Table 1

Baseline characteristics of the study population.

Characteristics/parameter	Esomeprazole + MC ($n = 26$)	Botulinum toxin A ($n = 20$)	P
Age	48.34 $\pm$ 7.38	48.10 $\pm$ 8.28	0.123
Male patients, n(%)	24(92.31)	19(95.00%)	0.359
BMI, Kg/m ²	23.55 $\pm$ 2.42	23.46 $\pm$ 2.14	0.129
Course	12.15 $\pm$ 15.81	10.35 $\pm$ 10.24	0.443
Fat diet	18(69)	12(60)	0.640
GERD ratio, n(%)	4(15.38)	5(25.00)	0.803
RSI ratio, n(%)	10(38.46)	8(40)	0.104
RFS ratio, n(%)	15(58)	12(60)	0.154

up visits, and 10 of them were cured after subsequently being treated with esomeprazole with mosapride citrate (Figs. 2 and 3). The average interval time was 3.1 (range) months (1–6) months (Table 2).

3.1. Efficacy

There were no differences in the pre-treatment symptom scores between patients in the two groups. The LPRD symptom scores for trachyphonia, clearing the throat, nagging cough, and pharyngeal abnormal sensations improved in both groups. Evaluation of the esomeprazole with mosapride citrate group at the baseline, 1, 2-month follow-ups demonstrated statistically significant improvement in the symptoms of LPRD. However, there were no statistically significant improvements at 3-month and 6-month follow-ups. In the group treated with both botulinum toxin A, trachyphonia, clearing the throat, nagging cough, and abnormal pharyngeal sensations showed statistically significant improvements from baseline, to 1-month follow-up, but with no statistically significant improvement at 2 subsequent follow ups. The LPRD symptoms scores were much lower in esomeprazole with mosapride citrate group than in the botulinum toxin A group (Fig. 4).

No patients experienced infection or death. The recorded post-treatment symptoms after therapy resolved with intervention within 6-month weeks with a statistically significant improvement in the esomeprazole with mosapride citrate group (Table 3).

4. Discussion

VPGs has been observed 10 to 20 times more common in men than in women [13]. In our series, they were 14 times more common (43 men but only three women). How women are protected against VPGs is unknown; however, the presence of posterior chink in women at vocal process during phonation might help explain this [13].

The association between gastric acid reflux and VPGs and the deleterious effects of acid and pepsin to the mucosa of the upper airway tract have been documented in animal models [14]. In 1968, Delahunty [15] reported the formation of laryngeal granuloma in the canine vocal cord. They induced the granuloma by placing a cotton ball moistened with gastric juice on the canine vocal cord. The data in the present study confirm that extra-esophageal reflux is more common in patients with granulomas than in asymptomatic healthy subjects. More than 50% of the rats in another study with both gastric acid reflux and mechanical injury of the vocal cord mucosa developed laryngeal granulomas despite experiencing the same type and degree of injury [16,17]. Although, LPRDs are thought as an important cause of VPGs by many people [2,6], but RSI, RFS and gastroesophageal reflux disease questionnaire (GERDQ) are simply used as assist diagnosis and prognostic [18], because of their subjectivity. In our study, only 18 patients (39%) were diagnosed with LPRD based on the RSI.

Ma et al. [19] analyzed the treatment of 168 with VPGs, and found that the lesions only disappeared in 41.3% of the patients who were given PPI, but Karkos et al. [20] believed that anti-reflux treatment

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