



Vocal Hygiene Education Program Reduces Surgical Interventions for Benign Vocal Fold Lesions: A Randomized Controlled Trial

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Objectives/Hypothesis: Vocal fold polyps and nodules are common benign laryngeal lesions. Currently, the Japanese health insurance system covers surgical interventions. However, the establishment of more cost-effective conservative methods is required, because healthcare costs are viewed as a major concern, and the government and taxpayers are demanding more economical, effective treatments. In this situation, more suitable vocal hygiene education may be important for the success of cost-effective conservative treatment. In this study, we developed a novel reinforced vocal hygiene education program and compared the results of this program with those of previous methods of teaching vocal hygiene.

Study Design: Multicenter randomized controlled trial.

Methods: Patients who visited a National Hospital Organization (NHO) hospital for the surgical indication of hoarseness were included in the study. Before undergoing surgery, 200 patients with benign vocal fold lesions (vocal fold polyps/nodules) were enrolled and randomly allocated to the NHO-style vocal hygiene educational program (intervention group) or control education program (control group). Two months after enrollment, the patients in both groups underwent laryngeal fiberoptic examinations to determine whether the benign lesions had resolved or whether surgery was indicated for the vocal fold polyps/nodules.

Results: After 2 months, in the intervention group, the proportion of lesion resolution (61.3%) was significantly greater than that in the control group (26.3%) ($P < .001$, Fisher exact test).

Conclusions: Our results clearly indicate that the quality and features of the education program could affect the outcome of the intervention. We found that a reinforced vocal hygiene education program increased the rate of the resolution of benign vocal fold polyps and nodules in a multicenter randomized clinical trial.

Key Words: Vocal hygiene, vocal fold polyps, vocal fold nodules, cost-effective conservative methods, National Hospital Organization-style vocal hygiene education program, multicenter randomized clinical trial.

Level of Evidence: 1b.

Laryngoscope, 128:2593–2599, 2018

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Editor's Note: This Manuscript was accepted for publication on June 5, 2018.

Makoto Hosoya, Rika Kobayashi, Mihiro Takazawa, and Koichi Tsunoda wrote the manuscript. Koichi Tsunoda and Akiko Kada designed this study. Makoto Hosoya, Rika Kobayashi, Mihiro Takazawa, Koichi Tsunoda, and Akiko Kada analyzed and interpreted the data. Makoto Hosoya, Toyota Ishii, Masamitsu Senarita, Hiroyuki Kuroda, Hayato Misawa, Fujinobu Tanaka, Tetsuya Takiguchi, Masatsugu Tashiro, Sawako Masuda, Sho Hashimoto, Fumiyouki Goto, Shujiro Minami, Nobuko Yamamoto, Ryoto Nagai, Akiko Sayama, Takeshi Wakabayashi, Keitaro Toshikuni, Rumi Ueha, Yoko Fujimaki, Mihiro Takazawa, Sotaro Sekimoto, Kenji Itoh, Takaharu Nito, and Koichi Tsunoda collected the data.

This study was registered as UMIN000016701 and was approved on December 5, 2014. Actual trial start date: February 16, 2015. Date of disclosure of the study information: March 6, 2015. Last follow-up date: March 31, 2017.

The trial was supported by the Japan National Hospital Organization Network Joint Research Fund "Kankakuki".

The authors have no other funding, financial relationships, or conflicts of interest to disclose.

Additional Supporting Information may be found in the online version of this article.

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DOI: 10.1002/lary.27415

INTRODUCTION

Japan's health indices such as life expectancy at birth are among the best in the world. However, at 8.5% the proportion of gross domestic product spent on healthcare was 20th among Organization for Economic Cooperation and Development members in 2008 and half as much as that in the United States.¹ However, even in Japan, current healthcare costs are viewed as a major concern, and the government and taxpayers are demanding more economical, effective treatments. Under the Japanese health insurance system, patients pay 30% of the total cost of each visit to a healthcare facility/treatment, and the remaining 70% is paid by the government.

Vocal fold polyps and nodules are common benign laryngeal lesions caused by vocal abuse or misuse. Previously, the Japanese health insurance system supported surgical interventions for such common benign laryngeal lesions. However, a trial of conservative treatment, including education in vocal hygiene or voice therapy with the avoidance of vocal abuse, is considered first-line treatment for those conditions before considering surgery in other developed countries. Several groups suggested that conservative treatment including vocal hygiene or voice therapy could be effective in treating vocal fold polyps and nodules.²⁻¹¹ Previous studies found that 21.1% to 56.3% improvement and 38% disappearance of vocal fold polyps could be achieved after conservative treatment with voice therapy.²⁻⁶ In cases of vocal fold nodules, some researchers achieved elimination or reduction of the lesions in 23% to 81.8% of patients,⁸⁻¹¹ and voice therapy was reported to prevent the recurrence of vocal nodules with or without surgery by other groups.^{12,13} In addition, we previously found that in 27 of 28 pediatric cases with vocal fold polyps and nodules, voice normalized after adolescence without surgery when the children were given instructions on vocal hygiene.⁸

The establishment of more effective conservative methods is required to avoid costly, invasive surgical interventions in patients with vocal fold polyps or nodules. Although vocal hygiene education combined with adequate voice therapy is frequently attempted as first-line therapy in patients with these conditions, there are differences in the capacities of medical facilities to provide vocal therapy, and substandard voice therapy regimens are generally ineffective. Unfortunately, in countries with few speech therapists (STs),^{14,15} including Japan, China, and some European countries, it is difficult to provide voice therapy, and surgical treatment, such as phonosurgery or fiberoptic forceps removal of vocal fold polyps and nodules, is more common because conservative treatment fails or is unavailable.

We believe that improved vocal hygiene education is important for the success of conservative treatment, although there is no strong evidence focusing on the features of vocal hygiene education programs leading to successful avoidance of phonosurgery for vocal fold polyps and nodules. We developed and refined a novel National Organization Hospital (NHO)-style education program for vocal hygiene under which physicians or STs teach patients how humans phonate and how to avoid vocal misuse while considering individuals' life style in a single,

Novel NHO-style vocal Hygiene Program

◆ Private, one-time lecture by a physician/speech therapist covering:

- 1) Anatomic and physiologic mechanisms of phonation, including functions of the nose and respiratory organs
- 2) Relationship between phonation and the auditory cortex (speech chain)
- 3) How and why vocal fold polyps and nodules form
- 4) Pathologic mechanisms of GER

◆ Instructions on maintaining general vocal hygiene

◆ Discussion of the relationship between the patient's individual lifestyle, his/her pathologic condition, and how to prevent it

With patients' families (if possible)

Supported by video program (for standardizing this method)

Fig. 1. Outline of the novel National Hospital Organization (NHO)-style vocal hygiene education program, conducted in the presence of family members if possible and supported by a videotaped lesson illustrating the standardized method. GER = gastroesophageal reflux.

private, short lecture supported by standardized videotaped lessons. We compared the results of this program with those of previous methods of teaching vocal hygiene.

MATERIALS AND METHODS

Trial Design

The research was a randomized controlled trial performed in 11 hospitals under the NHO group in Japan. The research protocol was approved by the NHO Tokyo Medical Center Ethics Committee (the institutional review board of Tokyo Medical Center), and the Ethics Committee of each of the other 10 participating NHO hospitals. Before enrollment, all patients signed written informed consent forms. This study was registered as UMIN000016701 (date of protocol fixation: December 5, 2014; anticipated trial start date: February 6, 2015; actual trial start date: February 16, 2015; date of disclosure of the study information: March 6, 2015; last follow-up date, March 31, 2017).

Patient Recruitment

From 2015, patients who visited one of 11 hospitals under the Japanese NHO for the first time for the surgical treatment of hoarseness were assessed for inclusion in this study. Patients who met the following selection criteria were enrolled: 1) a diagnosis of vocal fold polyp or nodule by fiberoptic and/or stroboscopy, 2) meeting the indications for phonosurgery due to hoarseness, 3) able to wait at least 2 months before surgery, 4) more than 20 years of age at the time of enrollment, and 5) agreeing to participate in the research and willingly signing a medical ethics application form. Exclusion criteria were: 1) examination (e.g., fiberoptic and/or stroboscopic study) results suggesting the presence of laryngeal cancer, laryngeal granuloma, tuberculosis, collagen disease, laryngeal cysts, or Reinke's edema; 2) requiring surgery within 2 months; and 3) deemed unsuitable for participation by their primary care physicians.

Patient Randomization

After providing explanations of the trial and receiving written informed consent forms, physicians telephoned the designated independent randomization center and reported the recruitment of patients. The center allocated patients to the

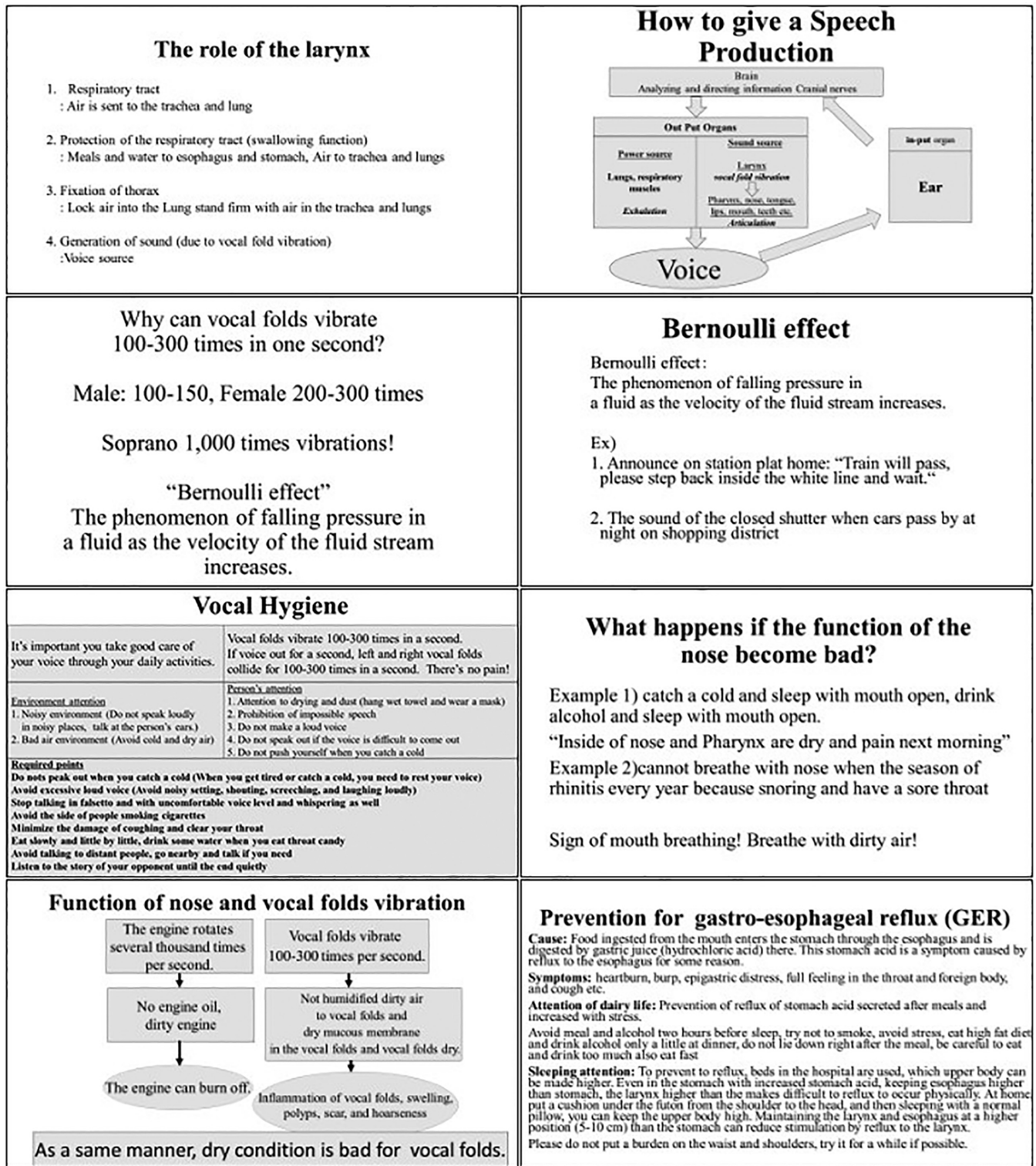


Fig. 2. Excerpts of the educated material for the intervention group.

intervention or control group using a random number meter. For example, the assignment of an even number meant that a patient was randomized to the intervention group, and an odd number meant randomization to the control group. Center staff informed participating physicians of the randomization status of their patients. The physicians were not blinded in this trial.

Intervention

All patients who were allocated to the intervention group received instructions on vocal education and vocal hygiene from physicians and STs, including the anatomic and physiologic mechanisms of phonation, supported by a videotaped lesson illustrating the standardized method (the novel NHO-style hygiene

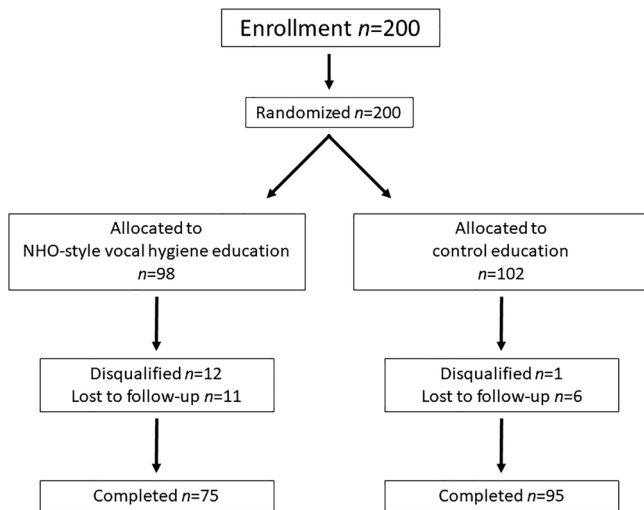


Fig. 3. Study design. NHO = National Hospital Organization.

educational program, which was mainly developed by departments of otorhinolaryngology of NHO hospitals). The instructions covered not only general vocal hygiene but also the functions of the nose and respiratory organs, the speech chain,¹⁶ and the pathologic mechanisms of gastroesophageal reflux (GER) and methods to prevent it (Figs. 1 and 2).¹⁷ Furthermore, physicians and STs discussed the relationship between individual lifestyles including smoking status, dietary habits, frequency of professional voice usage, and their pathologic condition with each patient and their families (if possible), because we believed that it was essential for patients to understand their conditions and become involved in efforts to cure them. After the program, physicians and STs confirmed that the patients understood the contents of the program, and they repeated the contents of the program and answered the questions until patients understood. All patients allocated to the control group were given documents explaining how to maintain their vocal hygiene (control vocal

hygiene program) (see Supporting Information 1, 2 and 3 in the online version of this article). In patients with obvious concomitant conditions, such as nasal allergy, rhinitis, tonsillitis, or GER, simultaneous treatment was administered.

Assessment of Outcomes

Two months after enrollment in the randomized controlled trial, the patients in both groups underwent laryngeal fiberoptic (and stroboscopic if needed) examinations to determine the resolution of benign lesions, which determined whether there was surgical indication or no surgical indication in those vocal fold polyps/nodules. The primary endpoint was proportion of lesion resolution (vocal cord polyps, vocal nodules). It was defined as the proportion of patients whose lesions have resolved in 2 months in registered patients. In this study, we defined *lesion resolution* as complete resolution of the lesion under endoscopic observation accompanying glottal closure without glottal incompetence. For sharing this criterion and definition, we had a meeting, and all physicians who were involved in the assessment of outcomes understood them. Secondary endpoints were changes in lesion (presence or absence of glottal gap, presence or absence of mucosal wave), maximum phonation time (MPT), and Voice Handicap Index (VHI)-10.¹⁸

Statistical Analysis

The proportion of lesion resolution for each group was compared by Fisher exact test. Logistic regression analysis was used for assessing the factors that might have affected the results. For changes in lesion (presence or absence of glottal gap, presence or absence of mucosal wave, if necessary), the proportion of disappearance for each group was calculated, and 95% confidence intervals of differences between groups was estimated.

For the power calculation, we calculated the sample sizes needed for this study as follows. First, we set the proportion of

Characteristic		NHO-style vocal hygiene education	Control
Age	Mean	52.7	55.3
	SD	18	16.2
Sex	Male	23 (26.7%)	33 (32.7%)
	Female	63 (73.3%)	68 (67.3%)
Side	Right	21 (24.4%)	29 (28.7%)
	Left	20 (23.3%)	29 (28.7%)
	Bilateral	45 (52.3%)	88 (47.1%)
Diagnosis	VFN	46 (53.5%)	42 (41.6%)
	Polyp	39 (45.3%)	59 (58.4%)
	VFN+Polyp	1 (1.2%)	-
Alcohol	No	52 (60.5%)	55 (54.5%)
	Yes	24 (39.5%)	46 (45.5%)
Smoking	No	64 (74.4%)	71 (70.3%)
	Yes	22 (25.6%)	30 (29.7%)

Fig. 4. Patient background characteristics in the intervention and control groups. There was no significant difference of the background characteristics between the two groups. VFN = vocal fold nodule; SD = standard deviation.

Group	Polyp/nodule resolution, no. (%)	
	Yes	No
NHO-style	46 (61.3%)	29 (38.7%)
Control	25 (26.3%)	70 (73.7%)

p<0.001

Fig. 5. Benign vocal fold polyp/nodule resolution in the intervention and control groups. Resolution was achieved in 61.3% (49.4%–72.4%) of patients in the National Hospital Organization (NHO)-style vocal hygiene education program, but in only 26.3% (17.8%–49.6%) of patients in the control group.

lesion resolution of control group as 15% under the effect of the handed documents. On the other hand, for the intervention group, we set the proportion of lesion resolution as 35% based on our previous small observations (48% resolution was achieved by intervention) and previous reports (38%–44% vocal cord polyps were resolved in 3 months^{4,5}). With the setting of the two-tailed α level of .05 and detection power of 0.85, it was calculated that 184 patients were required (92 patients per group). Finally, the samples size was set to 200 patients with consideration of the dropouts.

RESULTS

Two hundred patients with benign vocal fold lesions were enrolled in this study and randomly allocated to the intervention vocal hygiene education program (n = 98) or control education program (n = 102). After allocation, 12 patients were disqualified in the intervention group and one in the control group. The reasons for disqualification were: did not meet selection criteria (one who was misdiagnosed and one who did not sign the consent form, both in the intervention group); or met exclusion criteria (one showed evidence of laryngeal cancer, seven had laryngeal cysts, and two had Reinke's edema in the intervention group and one had collagen disease in the control group). During the 2-month period after study enrollment, 17 patients were lost to follow-up (11 in the

intervention group and six in the control group). In the intervention group, one patient changed hospitals for an unknown reason, two could not be followed-up due to another disease, four could not come for follow-up due to work-related issues, two could not come for follow-up due to personal issues, one could not come to the hospital for the 2-month follow-up, and one was lost to follow-up due to an unknown reason. In the control group, one subject changed hospitals because of his/her strong surgical demand, two could not be followed-up due to another disease, one could not come to follow-up because of a work-related issue, one could not come to the hospital for the 2-month follow-up, and one was lost to follow-up due to an unknown reason. Therefore, 170 patients, comprising 75 patients in the intervention and 95 in the control group, were included in the final analysis (Figs. 3 and 4). After the 2-month follow-up period, no patient was subsequently diagnosed with vocal fold malignancy. Patients were recruited from February 6, 2015 until March 31, 2017, and recruitment was stopped because the targeted number of patients was randomized.

After the 2-month follow-up period, the vocal fold lesions resolved in 71 patients (46 in the intervention and 25 in the control group), whereas 99 patients (29 in the intervention and 70 in the control group) were diagnosed as surgical candidates. In the intervention group, the proportion of lesion resolution was significantly greater than that in the control group ($P < .001$) (Fig. 5). Multivariable logistic regression analysis revealed that four factors were significant predictors of nodule/polyp resolution (Fig. 6). Significantly more patients allocated to the intervention vocal hygiene program achieved resolution and avoided surgery (odds ratio = 5.7). Patients diagnosed with vocal fold nodules were also more likely to achieve resolution of the condition than those diagnosed with polyps (odds ratio = 4.8). Being a nonsmoker showed a relatively lower risk (odds ratio = 0.3), but drinking alcohol showed a relatively higher risk (odds ratio = 2.3) for nodules/polyps to remain or progress. Moreover, we compared MPT changes and VHI-10 score changes between these two group. Both MPT and VHI-10 score were

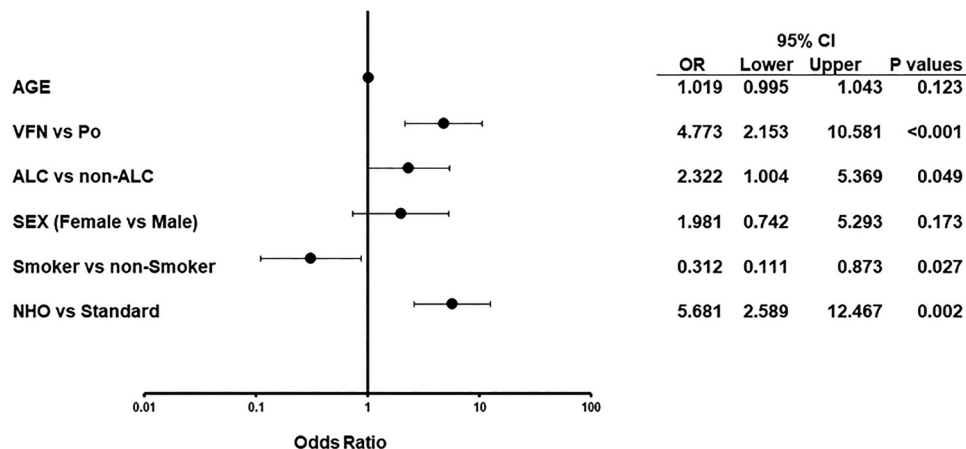


Fig. 6. Results of logistic regression analysis assessing factors affecting vocal fold nodule/polyp resolution. ALC = patients who consumed alcohol; CI = confidence interval; NHO = patients randomized to undergo the National Hospital Organization-style vocal hygiene program; non-ALC = patients who did not consume alcohol; OR = odds ratio; Po = polyp; VFN = vocal fold nodules.

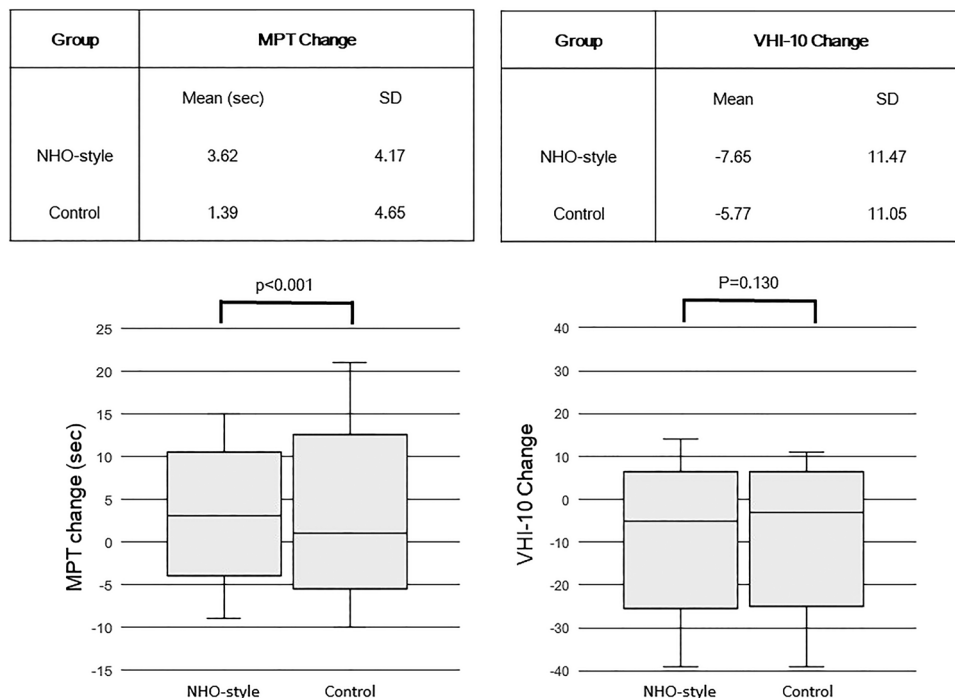


Fig. 7. Results of MPT and VHI-10 score change in the intervention and control group. MPT was significantly prolonged in the intervention group comparing with control group ($P < .001$), whereas no significant difference was observed in VHI-10 score change. MPT = maximum phonation time; NHO = National Hospital Organization; SD = standard deviation; VHI = Voice Handicap Index.

improved in both the intervention group and control group. MPT was significantly prolonged in the intervention group compared with the control group ($P < .001$), whereas no significant difference was observed in VHI-10 score between these groups ($P = .130$) (Fig. 7).

Finally, we performed sensitivity analyses because of the significant increased missing value in the intervention group. In this analysis, we assumed the worst results for the intervention group and the best results for the control group. Under this sensitivity analyses, in the intervention group, the proportion of lesion resolution was still significantly greater than that in the control group ($P = .035$).

DISCUSSION

Although vocal hygiene education has been provided for the treatment of benign vocal fold lesions following voice therapy or surgical intervention, how the quality of such education affected treatment outcomes remained unclear. Our study found that the novel NHO program of reinforced vocal hygiene education with feedback from physicians or STs was effective in achieving resolution of benign vocal fold lesions. Our results clearly indicated that the quality and features of the education program could affect the outcome of the intervention. Although the control group who received standard guidance on vocal hygiene showed a limited proportion of resolution (26.3%), the intervention group in the reinforced vocal hygiene education program performed with physicians or STs showed a higher proportion (61.3%) even without voice therapy.

In this study, the intervention program was shown to be independently effective in avoiding subsequent surgical intervention. This result indicates that the most benign vocal fold lesions could be resolved through education alone without voice therapy requiring frequent hospital visits by patients. A single visit for a sophisticated, focused vocal hygiene education program could therefore reduce the cost of frequent voice therapy interventions or surgical treatment.

So far, several reports showed the efficacy of vocal hygiene therapy on the benign vocal cord lesion or voice disorders,^{4,5,19-21} whereas several other studies pointed out the inadequacy of vocal hygiene as an independent therapy.²²⁻²⁴ Yun et al. reported that 38% of vocal cord polyps improved with vocal hygiene education, and concluded that patients who do not smoke and who have a polyp that is small in size have a much better chance of improving their voice by performing vocal hygiene.⁴ Jeong et al. reported that 43% of vocal cord polyps showed a clinically significant reduction in size, and 36% of them resolved completely without requiring surgery through vocal hygiene education.⁵ In this report we showed that up to 61.3% of the benign vocal cord lesions were resolved by a qualified, reinforced vocal hygiene education program and was more effective on the vocal nodule. Our results suggested that a nonsmoker is a much better candidate for the vocal hygiene education program. Although independent vocal hygiene education could not bring resolution in the all patients, and a subset of patients still needed surgical intervention, we showed that the quality of a vocal hygiene education program affected the resolution of the benign vocal cord lesion in a multicenter randomized clinical trial.

Moreover, avoiding the need for surgical intervention through this novel vocal hygiene program would benefit the healthcare system by decreasing healthcare costs. As an example, for the estimated cost of surgery to treat benign vocal fold nodules or polyps under the Japanese health insurance system, the government share would be around US\$2,800 to US\$3,500, and the individual share would be around US\$1,200 to US\$1,500 per patient. On the other hand, the cost of the NHO intervention is only around US\$300 to US\$90 per patient, respectively. Recently, progress in medical technology and the widespread adoption of advanced medical treatments have led to marked increases in medical expenditures, and reductions in those social expenses are pressing issues in many countries. It appears likely that avoidance of surgical interventions for vocal fold nodules/polyps using the novel program described here could contribute to reducing those medical expenditures by offering a noninvasive, relatively inexpensive alternative to surgery for the treatment of vocal fold polyps and nodules.

The limitations of this study include the lack of long-term follow-up, and thus it could not be concluded that the method would prevent recurrence over an extended period. To clarify this, a long-term observational study is planned in the future.

CONCLUSION

We found that a reinforced vocal hygiene education program effectively increased the rate of the resolution of benign vocal fold polyps and nodules relative to the control therapy in a multicenter randomized clinical trial.

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