

Duration of Effect and Associated Factors of Injection Laryngoplasty

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Summary: Objective. Injection laryngoplasty (IL) has become a mainstay in the treatment of unilateral vocal fold paralysis due to technical ease and avoidance of open surgery. The duration of IL effect depends on the injected material and has not been defined clearly. We aimed to define the effective duration of IL and to investigate the associated factors.

Methods. Fifty-nine patients who underwent IL for unilateral vocal fold paralysis were included. IL was performed using a cricothyroid membrane approach under local anesthesia. During follow-up, in cases that developed subjective hoarseness with objective glottic insufficiency, a second IL was performed, and loss of IL effect was recorded. The duration of IL was analyzed using Kaplan-Meier estimates, and the associations between duration of effect and various factors such as postinjection voice therapy, injected material, and cause of paralysis were investigated using log-rank test.

Results. Of 59 patients, 20 (33.9 %) received a second IL. The median time interval between the first and second IL was 3.3 months (95% CI, 0.4~27.8 months). The mean duration of effect after IL was 42.5 months (95% CI, 32.1~52.9 months), and the rate of persisting effect was 63.4% at 1-year after IL (1-year effect rate) and 59.4% at 2 years after IL. The 1-year effect rate was 80.8% in cases with postinjection voice therapy and 57.8% in those without postinjection voice therapy ($P = 0.084$). Injected material, DM, HTN, patient age and sex, and cause of paralysis had no effect on the 1-year effect rate.

Conclusions. The mean duration of IL effect was 42.5 months, and the rate of persisting effect was 63.4% at 1-year after IL. There were no significant factors affecting the duration of effect, although the duration tended to be slightly longer in cases with postinjection voice therapy. Further study with a prospective, randomized design is needed.

Key words: Vocal cord pArAlYsis—HoaRsenEss—LaryNgopLastY—VoIce QualiTy—VoicE trAiniNg.

INTRODUCTION

Glottal insufficiency related to uncompensated unilateral vocal fold paralysis (UVFP) can cause considerable morbidity including voice change, aspiration, and pneumonia.¹⁻³ Injury to the vagus nerve or recurrent laryngeal nerve (RLN) from neck or cardiothoracic surgery is a frequent cause of UVFP. Malignancies along the course of RLN in the neck, mediastinum, and lung are another major cause, and idiopathic cases are not rare.⁴

Various approaches including injection laryngoplasty (IL), medialization thyroplasty, and arytenoid adduction have been tried for UVFP.⁵ In the past, IL, which usually is performed with temporary materials such as hyaluronic acids, was considered a temporary procedure before the UVFP was proven to be permanent or recovered. However, it has become a mainstay in the treatment of both transient and temporary UVFP.^{6,7} However, the natural course after IL is not clear. The duration of IL effect depends on the

injected material. The effect of IL generally is considered to last several months, except for that of calcium hydroxyapatite, but has not been defined clearly.⁸ Recently, several factors such as timing of the procedure after development of UVFP or postprocedural voice therapy have been identified as related to IL effect longevity.⁹⁻¹¹

In this study, we aimed to define the duration of IL effect and to investigate the associated factors.

METHODS

Patients

This retrospective study included patients who underwent IL for UVFP at Ilsan Paik Hospital, Republic of Korea, between March 2014 and December 2020. This study was approved by the Institutional Review Board of Ilsan Paik Hospital (IRB File No. ISPAIK 2021-07-023). Patients with UVFP who had injection laryngoplasty were screened initially ($n=82$). Those who recovered from UVFP during follow-up after IL were excluded from the study ($n = 5$). Those who were followed-up for less than three months were also excluded ($n = 18$), but those who underwent second injection within three months were not excluded. A total of 59 patients was included in this study. Patient age ranged from 13 to 83 years, with a median of 63 years. Of the 59 patients, 31 were male and 28 were female. In terms of etiology of UVFP, surgery-related UVFP was most common (44.1%), followed by UVFP of unknown cause (33.9%). Duration of UVFP was less than six months in 34

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TABLE 1.
Patient Characteristics

Characteristics		Values
Age	Median (IQR) (year)	63 (53~72)
Gender	Male: Female	31:28
DM		17 (28.8%)
HTN		24 (40.0%)
Cause of paralysis	Identified	39 (66.1%)
	RLN invasion by tumor	4 (6.8%)
	RLN injury during operation	26 (44.1%)
	Brainstem lesion or surgery	2 (3.4%)
	Cranial nerve palsy	3 (5.1%)
	Trauma of intubation, TA	4 (6.8%)
	Unidentified	20 (33.9%)
Duration of paralysis	≤6 mo	34 (57.6%)
	>6 mo	25 (42.4%)
Injection material	Restylene	38 (64.4%)
	Artesense	21 (35.6%)
Post-injection VT		14 (23.7%)
Reinjection or AA		20 (33.9%)
Follow-up period	Median (IQR) (mo)	7.8 (3.3~18.9)

Abbreviations: AA, arytenoid adduction; IQR, interquartile range; TA, traffic accident; VT, voice therapy.

patients (57.6%) and greater than six months in 25 patients (42.4%) (Table 1).

Injection laryngoplasty (IL)

In all cases, IL was performed using a cricothyroid membrane approach under local anesthesia. A 23-gauge spinal needle was inserted through the cricothyroid membrane into the paralyzed vocal fold under fiberoptic guidance until the needle tip was observed at the lateral and anterior sides of the vocal process of the arytenoid cartilage. A position deep to the vocal ligament was targeted, and injection was performed until the paralyzed vocal fold was augmented and no glottic gap remained during phonation. The injected material was Restylene (Q-Med Corp, Uppsala, Sweden) in 38 patients (64.4%) and ArteSense (European Medical Contract Manufacturing B.V., Nijmegen, Netherlands) in 21 patients (35.6%).

Postinjection voice therapy

Fourteen patients (23.7%) underwent voice therapy after IL. The average number of sessions was eight, ranging from six to 10. Voice therapy was performed once per week by an experienced speech-language pathologist using direct and indirect voice therapy. Indirect therapy included self-recognition of voice problems and vocal hygiene education. Direct voice therapy encompassed a variety of voice facilitation techniques, including Lax Vox training, yawn-sigh, laryngeal massage, and resonance training. Specific therapeutic techniques were tailored to individual patients.

Voice analysis

Perceptual, acoustic, and aerodynamic assessments were performed before and after IL. The Multi-Dimensional Voice Program from the Computerized Speech Lab (CSL, Model 4150B; Kay Elemetrics Corp.) and Phonatory Aerodynamic System were used for acoustic and aerodynamic analyses. Preinjection and postinjection voice analyses were performed in 24 (40.7%) and 12 patients (20.3%), respectively. Each patient was seated in a quiet room, and a microphone was placed 3 cm from the mouth. They were asked to produce continuously the vowel sound /a/ at a comfortable pitch and volume and to read a standardized, phonetically balanced Korean passage ("Sancheek" passage).¹² Fundamental frequency, percentage of jitter and shimmer, noise-to-harmonics ratio (NHR), voice range profile (VRP), and maximum phonation time (MPT) were calculated. The speech-language pathologist assessed patient voice according to the overall grade-roughness-breathiness-asthenia-strain (GRBAS) scale. In addition, patients performed self-assessments using a culturally validated Korean version of the Voice Handicap Index (VHI) questionnaire¹³ before and after voice therapy.

Follow-up

Patients were followed after IL at three- to six-month interval. At each follow-up, laryngoscopic examination and subjective symptoms were assessed. Patients who were lost to follow-up within three months were excluded from this study, but those who underwent a second procedure within three months were not. Those who recovered from UVFP during follow-up also were excluded. The median follow-up period was 7.8 months. During follow-up, in cases where subjective hoarseness developed and objective glottic

insufficiency was observed with laryngoscope, a second IL or arytenoid adduction was performed.

Statistical analysis

The duration of IL effect was assessed using Kaplan-Meier estimates. The log-rank test was used to assess the factors associated with duration. SPSS software for Windows, version 17.0 (SPSS Inc., Chicago, IL) and R 3.6.1 for Windows were used for statistical analyses. All tests were two-sided, and $P < 0.05$ was considered statistically significant.

RESULTS

After IL, the G score of the GRBAS scale significantly decreased (1.4 ± 0.8) compared to before IL (2.8 ± 0.4 , $P < 0.001$). VHI total score improved after IL (from 60.9 ± 37.1 to 10.1 ± 12.6 , $P = 0.001$), as did maximum phonation time (MPT) (from 5.1 ± 3.5 to 9.7 ± 5.6 , $P = 0.005$). Jitter, shimmer, and NHR showed decreasing tendencies but no statistical significance (Table 2).

Of 59 patients, 20 (33.9%) underwent secondary procedures due to recurrence of glottic insufficiency; repeat IL was performed in all cases. After the second procedure, one patient underwent arytenoid adduction. The median time interval between first and second IL was 3.3 months, ranging from 0.4 to 27.8 months. Of the 20 second IL cases, 18 (90%) were performed within 1-year after first IL (Figure 1).

When the second IL was defined as the end of the first IL effect and the duration of effect was analyzed using the Kaplan-Meier survival model, the mean duration of effect was 42.5 months (95% CI, 32.1~52.9 months). The rate of persisting effect was 63.4% at 1-year after IL (1-year effect rate) and 59.4% at 2 years after IL (Figure 2).

TABLE 2.
Voice Outcomes after IL for Unilateral VFP

	Before IL	After IL	<i>P</i> -value
GRBAS G score	2.8 ± 0.4	1.4 ± 0.8	<0.001
GRBAS R score	1.3 ± 1.1	0.5 ± 0.5	0.055
GRBAS B score	2.7 ± 0.7	1.2 ± 1.0	<0.001
GRBAS A score	0.8 ± 1.3	0.1 ± 0.3	0.087
Jitter	4.0 ± 3.0	2.0 ± 1.7	0.087
Shimmer	8.3 ± 5.5	4.8 ± 3.2	0.154
NHR	0.2 ± 0.2	0.2 ± 0.1	0.178
MPT	5.1 ± 3.5	9.7 ± 5.6	0.005
VHI total score	60.9 ± 37.1	10.1 ± 12.6	0.001
VHI_F score	18.7 ± 14.3	2.2 ± 3.5	0.002
VHI_P score	23.3 ± 12.3	5.2 ± 6.1	<0.001
VHI_E score	18.9 ± 12.7	2.6 ± 3.7	0.001

Notes: Values are expressed as mean $\pm$ standard deviation. Bold values are statistically significant.

Abbreviations: IL, injection laryngoplasty; MPT, maximum phonation time; NHR, noise-to-harmonics ratio; VHI, voice handicap index; VHI_E, VHI emotional domain; VHI_F, VHI functional domain; VHI_P, VHI physical domain.

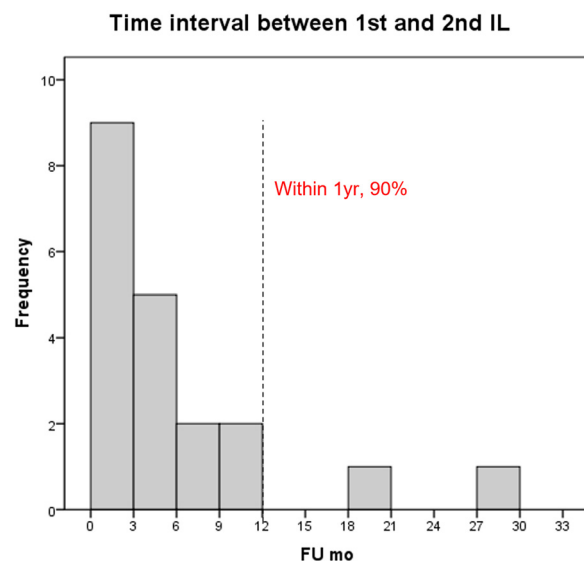


FIGURE 1. Time interval between first and second IL. Second IL was performed in 20 cases (33.9%). The median time interval between first and second IL was 3.3 mo, ranging from 0.4 to 27.8 mo. Of 20 cases, 18 (90%) were performed within one year after first IL. “(For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)”

The 1-year effect rate was 80.8% in cases with postinjection voice therapy and 57.8% in those without postinjection voice therapy ($P = 0.084$, Figure 3A). Second IL was performed in four of 14 cases (28.6%) with voice therapy and 16 of 45 cases (35.6%) without voice

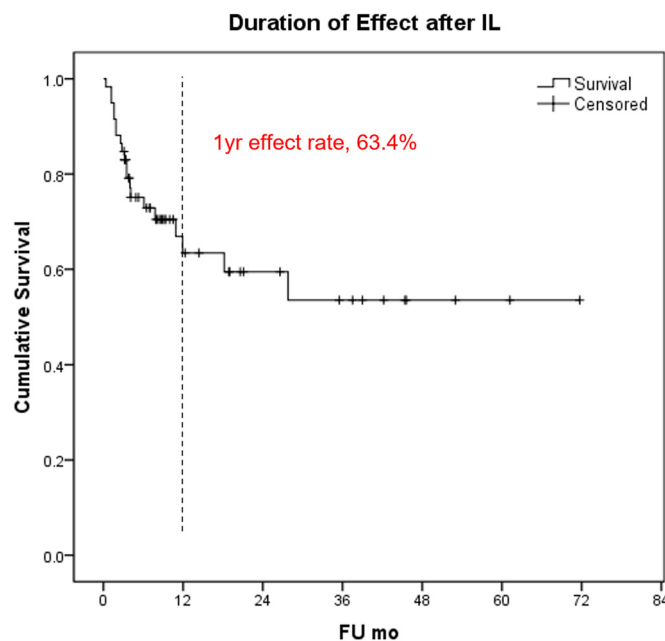


FIGURE 2. Duration of effect after IL. The mean duration of effect was 42.5 months (95% CI, 32.1~52.9 months). Rate of persisting effect was 63.4% at one year after IL (1-y effect rate) and 59.4% at 2-y after IL. “(For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)”

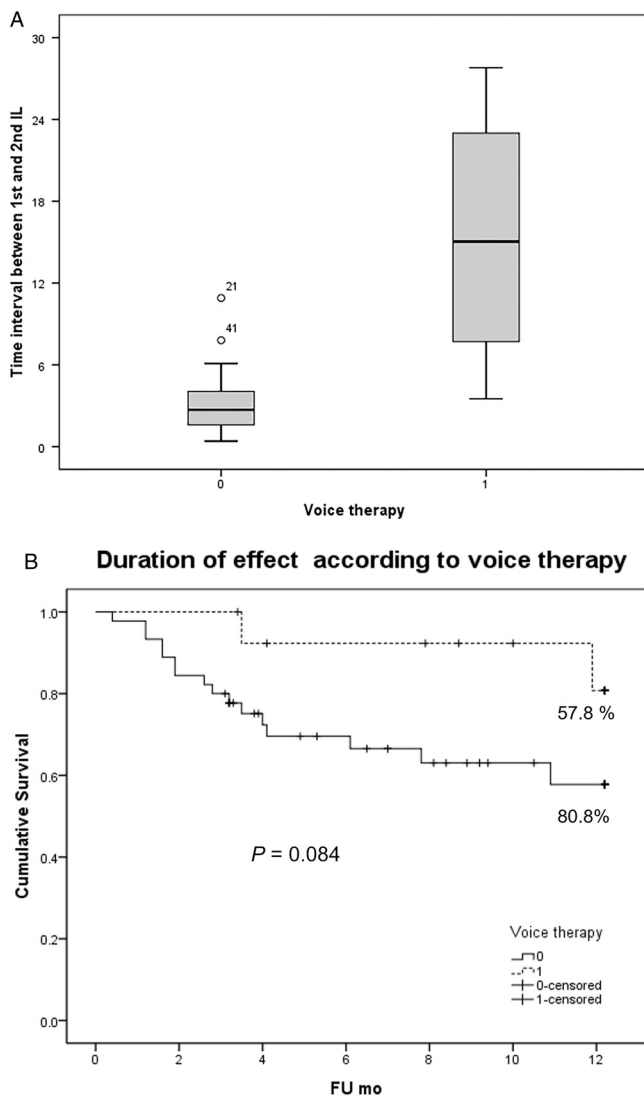


FIGURE 3. Longevity of IL according to post-injection voice therapy. (A) The 1-y effect rate was 80.8% in cases with post-injection voice therapy and 57.8% in those without ($P = 0.084$). (B) In cases with voice therapy, the median time interval between first and second IL was 15.1 months, while it was 2.7 mo in those without voice therapy ($P = 0.091$). “(For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)”

therapy. In cases with voice therapy, the median time interval between first and second IL was 15.1 months, while it was 2.7 months in those without voice therapy (Figure 3B). The one-year effect rate was 52.7% in male patients and 73.9% in female patients ($P = 0.091$). Injection material, duration of paralysis, DM, HTN, patient age, and cause of paralysis were not associated with the duration of effect after IL (Table 3).

DISCUSSION

Since IL first was described by Brunings in 1911, various injection materials such as collagen, hyaluronic acid (HA),

TABLE 3.
Duration of Effect According to Various Factors

		One-year effect rate	P-value
Voice therapy	Performed	80.8%	0.084
	Not performed	57.8%	
Injection material	Restylene	63.2%	0.844
	Artesense	67.5%	
Duration	≤6 mo	56.8%	0.291
	>6 mo	72.1%	
Cause	Unidentified	59.1%	0.948
	Identified	64.4%	
DM	Absent	61.9%	0.948
	Present	68.6%	
HTN	Absent	65.2%	0.250
	Present	58.1%	
Gender	Male	52.7%	0.091
	Female	73.9%	
Age (years)	≤60	63.6%	0.878
	<60	63.6%	

autologous fat, and calcium hydroxyapatite have been introduced.^{8,14,15} The duration of effect can be different according to injection material. Calcium hydroxyapatite is a long-lasting injection material that is approved by the US Food and Drug Administration.¹⁶ Rosen et al reported significant improvement and moderate improvement in 67% and 81% of patients, respectively, at 12 months after injection.¹⁷ However, a substantive portion of patients was lost to follow-up or unavailable for analysis at 12 months after injection. In many studies, loss to follow-up is the main reason why the duration of IL effect cannot be assessed clearly. HA is a component of the extracellular matrix, and the viscoelastic properties of vocal folds after HA injection are similar to those of the healthy vocal fold in animal studies.¹⁸ Due to its properties and safety, HA has become another popular injection material for IL. HA is considered a short-lasting material. Although there is debate on the long-term effect of IL with HA, some studies have reported that the effect lasted longer than 12 months in a substantial portion of patients (>50%).¹⁹⁻²¹ ArteSense consists of polymethyl methacrylate (PMMA) microspheres and bovine collagen. It was introduced as a relatively long-lasting injection material because PMMA microspheres are not phagocytosed and fosters synthesis of own collagen.^{22,23} Min et al reported persisting effect at 12 months follow-up in 48% of all patients and 53% of patients with permanent UVFP.²⁴ In an *in vivo* study, the dimension of the augmented region was maintained in the Artecoll group for nine months after injection, while up to 30% of the augmented dimension was resorbed in the HA group.²⁵

In this study, the 1-year effect rate after IL was 63.4% overall, 63.2% in the HA group, and 67.5% in the ArteSense group, consistent with previous results. Despite the theoretical superiority, there was no statistically significant difference between the two injection materials ($P = 0.844$). The

effect of IL was maintained for longer than 1-year in more than half of patients, although the injection material was not permanent, such as calcium hydroxyapatite.

The duration of paralysis, timing of injection after onset of UVFP, also can affect the duration of effect. In terms of duration of paralysis, there have been many studies related to the effect on IL. In several studies, the late injection group (>6 months) had a significantly higher rate of open surgery than did those who underwent early injection (<6 months).^{11,26} In another study on IL after thyroidectomy, acoustic parameters were worse in the late injection group (>3 months) than in early injection group (<3 months).¹⁰ However, in the present study, there was no significant difference in rate of secondary procedures within 1-year ($P = 0.291$). The 1-year effect rate was 56.8% in the early injection group (<6 months) and 72.1% in the late injection group (>6 months). A previous study has suggested that early injection allows for a better final resting position once synkinetic reinnervation is complete and tactile stimulation from physical contact with the contralateral mobile vocal cord.¹¹ However, a recently paralyzed vocal cord is more likely to undergo further laryngeal muscle atrophy than is a vocal cord paralyzed for a long duration. The association between duration of paralysis and duration of effect has not been determined. There could be a selection bias in this kind of non-randomized studies, and significant follow-up losses can reduce the analysis accuracy. In this study, five of 34 patients (14.7%) in the early injection group and nine of 25 patients (36%) in the late injection group underwent second IL.

We also investigated the association between postinjection voice therapy and duration of IL effect. In a previous study, voice parameters significantly improved after postinjection voice therapy than at one month after IL alone. In patients without postinjection voice therapy, the voice parameters at six months after IL were not significantly different from those at one month after IL.⁹ Previous studies have reported the efficacy of voice therapy as an intervention for UVFP.²⁷⁻²⁹ After IL, the position of the paralyzed vocal fold is improved for voice therapy. Therefore, the efficacy of voice therapy can improve. Improved vocal contact after IL and postinjection voice therapy could affect the duration of effect after IL. In this study, postinjection voice therapy was performed in 14 of 59 patients (23.7%). The 1-year effect rate tended to be slightly higher (80.8%) in cases with post-injection voice therapy than in those without (57.8%), although there was no statistical significance ($P = 0.084$). Significance might have been achieved if the study was randomized and the selection bias was controlled. Also, in cases with postinjection voice therapy, the interval between first and second IL treatments was longer. The median time interval between first and second IL was 15.1 months in cases with voice therapy and 2.7 months in those without voice therapy (Figure 3B).

There were several limitations in this study. First, this was a retrospective cohort study. Parameters such as voice therapy, injection material, and duration of paralysis were not

randomized. More information could have been obtained if a prospective, randomized study, blinded to injected materials, had been conducted. Next, a sizeable portion of patients was lost to follow-up. Though this loss could be attributed to absence of discomfort, the lost patients might have moved to another hospital. Therefore, we performed a survival analysis. Nevertheless, if follow-up duration and interval were standardized, data analysis would be more efficient. Lastly, the outcome measurement could be improved with follow-up voice analysis. In this study, the outcome measurement was need for a secondary procedure. With the standardized follow-up, if the outcome measurement was reinforced with follow-up voice analysis, the result would be more reliable.

CONCLUSION

IL has become a mainstay of treatment for UVFP due to its relative technical ease and no need for open surgery. However, the duration of effect is not clear. In this study, the mean duration of effect was 42.5 months, and the rate of persisting effect was 63.4% at 1-year after IL. There were no significant factors affecting the duration of effect, although the duration tended to be slightly longer in cases with post-injection voice therapy. Further study with prospective, randomized design is needed.

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