Comparison between functional outcomes in patients with unilateral vocal fold paralysis undergoing injection laryngoplasty under general anesthesia versus local anesthesia

Amr R. El-Badrawy[b], Hassan M. El-Hoshy[b], Ayatallah R. Sheikhany[a], Wael S.A. El-Rehim[c]

[a]Lecturer of phoniatrics, Ent Department, [b]Professor of Otorhinolaryngology, ENT Department, [c]ENT specialist - Police Hospitals, Alahrar Teaching Hospital, Giza, Egypt

Correspondence to Ayatallah R. Sheikhany, MD, Department of Phoniatrics, Faculty of Medicine, Cairo University, Cairo, 12341, Egypt. Tel: +20 128 401 4401; e-mail: ayasheikhany@gmail.com

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Introduction
Injection laryngoplasty (IL) continues to evolve, as new techniques, approaches, and injection materials are continuously being developed. Although it was performed under general anesthesia in the operating room, IL is now increasingly being performed in an office-based setting.
Aim
The aim of this study was to compare functional voice outcomes in patients with unilateral vocal fold paralysis undergoing injection laryngoplasty local versus general anesthesia.
Patients and methods
A prospective interventional study was done to compare functional outcomes and patient satisfaction between group A (15 patients) with unilateral vocal fold paralysis undergoing injection laryngoplasty under local anesthesia, versus group B (15 patients) with unilateral vocal fold paralysis undergoing injection laryngoplasty under general anesthesia, by analyzing total Arabic Voice Handicap Index (VHI) scores and subscale scores preoperatively and post operatively.
Results
All results obtained in this study showed that there was no significant difference for the functional outcomes and patient satisfaction obtained for both groups under study.
Conclusion
In conclusion, IL under local anesthesia gives similar results as general anesthesia regarding functional outcomes and patient satisfaction of voice quality by themselves as well as by using the voice handicap index.

Keywords:
functional outcomes, injection laryngoplasty, unilateral vocal fold paralysis, voice handicap index

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Introduction

The inability to communicate with ease is the most notable function that is affected in a handicapped voice. Inability to communicate with confidence and ease can affect every facet of human experience, from education to gaining employment to forming relationships [1].

Unilateral vocal fold paralysis (UVFP) occurs from a dysfunction of the recurrent laryngeal or vagus nerve innervating the larynx. It causes a characteristic breathy voice often accompanied by swallowing disability, a weak cough, and the sensation of shortness of breath. This is a common cause of neurogenic dysphonia. When this paralysis is properly evaluated and treated, normal speaking voice is typically restored [2].

Symptoms of UVFP include hoarseness of voice, breathy voice, inability to speak loudly, limited pitch and loudness variations, voicing that lasts only for a very short time (around one second), choking or coughing while eating, and possible pneumonia owing to food and liquid being aspirated into the lungs [3].

The use of a structured questionnaire to evaluate voice outcomes and quality of life in these patients is required. One of the most widely used dysphonia-specific quality-of-life questionnaire is the voice handicap index (VHI) [4].

The VHI comprises a series of questions targeting the patient's perception of her/his own voice. It is a useful tool to help gain insight into the emotional, physical, and functional components of the voice problem as well as to measure therapeutic outcomes [5].

The rationale for medializing a paralyzed true vocal fold is to restore glottis competence to improve voice quality and prevent aspiration, and the optimal time and method of vocal fold paralysis management are controversial. Factors contributing to the controversy include uncertainty regarding the possible return of function and concern about the permanency of some procedures. Initial treatment options for UVFP include observation for spontaneous return of function, voice therapy, and/or temporary vocal fold injection (medialization and augmentation) [6].

Vocal fold injection is a procedure that has over a 100-year history but was rarely done as short as 20 years ago. A renaissance has occurred with respect to vocal fold injection owing to new technologies (visualization and materials) and new injection approaches [7].

Although phonosurgical vocal fold injection is traditionally performed under general anesthesia, the procedure can be performed in an office-based setting [8].

Injection augmentation remains a safe, effective, and clinically practical treatment with a high rate of success, whether performed in the awake or asleep patient. Both awake injection and injection under general anesthesia retain a clinical role, subject to considerations of indication, physician preference, and patient safety and convenience. We expect injection augmentation to remain a mainstay technique in voice rehabilitation [9].

Patients and methods

This prospective nonrandomized interventional study was conducted on 30 patients with UVFP attending the outpatient clinic of the ENT Department, Kasr El Aini Hospital, Cairo University, and ENT Department of the Aguoza Police Authority Hospital.

Patients

During the period of 6 months from December 2014 to June 2015, 30 patients were examined, including 12 males and 18 females, aged from 18 to 60 years of age, who came complaining of dysphonia and were diagnosed to have UVFP.

Inclusion criteria

The inclusion criteria were UVFP for more than 6-month duration, patients older than 18 years, and patients who received voice therapy for at least 6 months.

Exclusion criteria

The exclusion criteria were history of previous injection, patients younger than 18 years, anatomical abnormalities in larynx, previous known allergy to the injectable material, and previous surgeries on the vocal folds.

Methods

All the patients were subjected to the following protocol:

(1) History taking: patient interview and full history taking.
(2) General examination.
(3) Local laryngeal examination and voice assessment including the following:
    (a) Laryngoscopic examination: through indirect examination in ENT clinic as well as rigid/flexible laryngoscopic examination done in the phoniatric unit.
    (b) Voice assessment:
        (i) Auditory perceptual assessment: grade of dysphonia, type of dysphonia, loudness, and pitch.
        (ii) VHI: it measures the physical, functional, and emotional aspects of the voice. The threshold for significant change was based on values determined by Jacobson *et al*. [5] during the validation of the questionnaire. It is made up of 30 questions, broken down into three groups:
        [1] The functional domain which includes statements that describe the 'impact of a person's voice disorders on his or her daily activities'.
        [2] The emotional domain indicates the patient's 'affective responses to a voice disorder'.
        [3] The physical domain is statements representing self-perceptions of laryngeal discomfort and voice output characteristics [10].
        Each one of these subitems has 10 specific situations or questions, identified by their frequency of occurrence through a progressive numeric scale: 0 (never), 1 (almost never), 2 (sometimes), 3 (almost always), and 4 (always).
        Then a partial scoring for each one of the three parameters and one total score are obtained, the latter varying between 0 and 120. Such scorings are directly associated with the level of disability or restriction associated with the voice and indicate the degree of handicap the person is experiencing secondary to their voice problems.

(4) Investigations (preoperative workup):
   (a) Radiological study (computed tomography scan of base of the skull, neck, and upper chest).
   (b) Laboratory diagnosis.
(5) Consent: an informed consent for the procedure was obtained preoperatively including all reasonable vocal expectations, limitations, and potential surgical complications.
(6) Material for injection: in this study, calcium hydroxylapatite (CaHA) was used for injection and medialization of the vocal folds.

All the 30 patients were subjected to injection laryngoplasty (IL), but the patients are divided into two groups based on anesthesia:

(1) Group A: it included 15 patients who underwent IL under local anesthesia.
(2) Group (B): it included 15 patients who underwent IL under general anesthesia.

Decision of injection under local or general anesthesia was made according to the following patient-related criteria:

(1) Cooperativeness.
(2) Agreement.
(3) Fitness for surgery under general anesthesia or not (laboratory and general conditions).

Operative details

Group A: injection under local anesthesia

Patient positioning: the patient was positioned upright in the examination chair with head support.

Anesthesia: topical anesthesia included xylocaine spray 10% to the oral cavity, oropharynx, and base of tongue. Under flexible laryngoscope guidance, 4% lidocaine is dripped onto the larynx. The cricothyroid membrane is palpated, marked horizontally with a pen, and then 0.5 ml of 1% lidocaine hydrochloride with 1 : 100 000 units is injected subcutaneously in the area of cricothyroid membrane.

Surgical technique of injection: an assistant performs flexible endoscopic nasolaryngoscopy for guidance of the injection.

The injecting material CaHA (Radiesse) syringe is attached to a 4-cm long 22-G needle and then introduced perpendicularly through the cricothyroid membrane in the midline. Once the tip passes in the subglottic area, it is directed nearly straight up and vertically toward the vocal fold to be injected. The tip of the needle can be moved back and forth rapidly several times over a short distance until the needle tip is seen indenting the mucosa of vocal fold. Once the needle position is confirmed, vocal fold injection is started slowly in the paraglottic space. The end point for injection is determined by the endoscopic appearance of the vocal fold as well as the patient's voice. The amount of CaHA to be injected ranged usually from 0.5 to 1.5 ml depending upon the glottic gap. Good visualization is essential at all steps of the procedure.

Postoperative care and follow-up: the patients were monitored for 20 min after the procedure and given instructions to avoid oral food or liquid intake for at least 1 h. Voice rest is prescribed for 1 day. Hydration and humidification were advised.

Group B: injection under general anesthesia

Patient positioning: the optimal position is supine with the neck flexed and the head extended (Boyce position, flexion of the cervical spine, and extension of the atlanto-occipital joint). The teeth and alveolar ridge are protected, with atraumatic insertion of adequately sized laryngoscope. The largest laryngoscope possible should be used to allow the surgeon the maximal amount of exposure for operating at the level of the vocal folds.

Anesthesia: these procedures require general anesthesia with complete relaxation of the patient throughout the procedure. A small endotracheal tube (size: 5.0–5.5) should be placed. Not only does the smaller tube improve visualization for the surgeon, it also diminishes the chance of injury to the vocal fold on intubation.

Surgical technique of injection: after insertion of adequately sized laryngoscope, the degree of glottic incompetence is assessed through a combination of preoperative awake stroboscopy and intraoperative visualization with microlaryngoscopy and 0, 30, and 30° angled telescopes.

This provides direct access to the vocal fold and allows for precise needle placement along the superior arcuate line with a direct, linear trajectory. The needle is used to inject the upper surface of the paralyzed vocal fold at the posteromedial aspect until the body of the vocal fold bulges and the free edge almost reaches midline.

Postoperative care: complete voice rest for 1 day, along with hydration and humidification were advised with administration of analgesia, and the patient was discharged on the next day.

Postoperative follow-up of both groups

The VHI was repeated after 4 weeks from the surgery. The total scores and subscale scores were calculated.

Laryngeal examination was done with flexible nasopharyngeal laryngoscopy after 4 weeks to assess the glottic gap and assess the medialization results.

Results

Table 1 presents the causes of UVFP of the patients under study. The most common cause of UVFP in the patients under study was thyroid surgeries (70%) of patients, and other causes are viral infection (17%), neck surgeries (3%), and unknown cause (10%).

Table 2 presents the distribution of the side of the paralyzed vocal fold among patients in both groups A and B. Left vocal fold paralysis was more common (66% of cases) than paralysis of right vocal fold (34% of cases) in patients under study.

Table 3 presents the preoperative and postoperative subscales scores (functional, physical, and emotional) and total scale score of VHI of group A. There is a decrease in all domains as well as total VHI scores in the patients of group A postoperatively when compared with preoperative scores. The degree of handicap was severe and moderate preoperatively and became minimal postoperatively. The total score ranges from 32 to 102, with 13 (87%) patients severely handicapped and two (13%) moderately handicapped preoperatively. In the postoperative VHI scores of group A, most of the patients had a reduction in total and subscale VHI scores with marked decrease in the number, severity, and grade of handicapping. Postoperative total scores greatly decreased, where 7% of the patients were severely handicapped, 20% of the patients were moderately handicapped, and 73% were minimally handicapped.

Table 4 presents the preoperative and postoperative subscale scores (functional, physical, and emotional) and total scale score of VHI of group B. There is a decrease in all domains as well as total VHI scores in the patients of group B postoperatively when compared with preoperative scores. The degree of handicap was severe and moderate preoperatively and became minimal postoperatively. In postoperative VHI scores of group B, most of patients had a reduction in total and subscale scores with marked decrease in the number, severity, and grade of being handicapped. Postoperative total scores

Table 1 Causes of unilateral vocal fold paralysis of the patients under study

	Thyroid surgeries [*n* (%)]	Other neck surgeries [*n* (%)]	Viral infection [*n* (%)]	Idiopathic [*n* (%)]
All patients number=30	21 (70)	1 (3)	5 (17)	3 (10)

Table 2 Distribution of the side of the paralyzed vocal fold among patients in both groups A and B

	All patients (*N*=30) [*n* (%)]	Group A (*N*=15) [*n* (%)]	Group B (*N*=15) [*n* (%)]
Paralysis			
Left VF	20 (66)	11	9
Right VF	10 (34)	4	6

VF, vocal fold.

Table 3 Preoperative and postoperative subscales scores (functional, physical, and emotional) and total scale score of voice handicap index of group A

Group A (injection laryngoplasty under local anesthesia)								
	Preoperative VHI scoring				Postoperative VHI scoring			
Case number	Functional	Physical	Emotional	Total	Functional	Physical	Emotional	Total
1	35	38	29	102	15	14	16	45
2	12	12	8	32	4	6	2	12
3	20	21	16	57	20	21	16	57
4	15	24	12	51	11	13	10	34
5	17	22	13	52	8	9	6	23
6	20	20	27	67	11	6	13	30
7	26	27	9	62	11	17	4	32
8	28	28	27	83	18	15	14	47
9	24	20	22	66	9	13	10	32
10	31	20	20	71	31	20	20	71
11	27	22	8	57	10	7	5	22
12	11	12	23	46	8	7	5	20
13	20	20	22	62	10	8	11	29
14	12	16	14	42	4	2	4	10
15	17	21	13	51	5	7	4	16

VHI, voice handicap index.

Table 4 Preoperative and postoperative subscales scores (functional, physical, and emotional) and total scale score of voice handicap index of group B

Group B (injection laryngoplasty under general anesthesia)								
	Preoperative VHI scoring				Postoperative VHI scoring			
Case number	Functional	Physical	Emotional	Total	Functional	Physical	Emotional	Total
1	26	29	9	64	11	17	4	32
2	25	22	8	55	9	7	5	21
3	24	19	22	65	9	13	9	31
4	16	15	8	39	4	5	3	12
5	31	32	29	92	13	16	11	44
6	17	19	13	49	6	6	6	18
7	17	22	13	52	8	8	7	23
8	25	21	24	70	24	18	18	60
9	19	30	23	72	15	18	16	49
10	20	19	27	66	11	6	12	29
11	9	16	14	39	2	4	2	8
12	15	26	12	53	11	14	7	32
13	21	18	19	58	12	8	11	31
14	28	29	26	83	18	17	14	49
15	11	14	21	46	7	5	6	18

VHI, voice handicap index.

Table 5 Comparison of the results of preoperative and postoperative voice handicap index scores in group A

Group A: results									
	Preoperative scores				Postoperative scores				
	Mean	SD	Minimum	Maximum	Mean	SD	Minimum	Maximum	*P* value
Functional	21.00	7.31	11	35	11.67	7.06	4	31	0.0001
Physical	21.53	6.39	12	38	11.00	5.62	2	21	0.0001
Emotional	17.53	7.21	8	29	9.33	5.54	2	20	0.0001
Total	60.07	17.02	32	109	32.00	16.95	10	71	0.0001

Table 6 Comparison of the results of preoperative and postoperative voice handicap index scores in group B

Group B: results									
	Preoperative scores				Postoperative scores				
	Mean	SD	Minimum	Maximum	Mean	SD	Minimum	Maximum	*P* value
Functional	20.27	6.26	9	31	10.67	5.51	2	24	0.0001
Physical	22.07	5.80	14	32	10.80	5.43	4	18	0.0001
Emotional	17.87	7.25	8	29	8.73	4.80	2	18	0.0001
Total	60.20	15.15	39	92	30.47	14.76	8	60	0.0001

greatly decreased, as 27% of the patients with moderate handicap grading became 73% (four patients) of the patients with mild handicap and no patient was severely handicapped.

Table 5 presents the comparison of the results of preoperative and postoperative VHI scores in group A. There was a highly significant difference in the postoperative VHI scores in comparison with the preoperative scores of group A.

Table 6 presents the comparison of the results of preoperative and postoperative VHI scores in group B. There was a highly significant difference in the postoperative VHI scores in comparison with the preoperative scores.

Table 7 presents the comparison between postoperative VHI score results in group A and group B. There was no significant difference in the mean values of total VHI scores and subscale scores in the patients of group A postoperatively as compared with postoperative scores of group B.

Table 8 presents the comparison of preoperative and postoperative data of group A and group B patients in the form of amount of CaHA (ml), postoperative gap between vocal folds by flexible nasolaryngoscopy [same

Table 7 Comparison between postoperative voice handicap index score results in group A and group B

	Group A				Group B				*P* value
	Mean	SD	Minimum	Maximum	Mean	SD	Minimum	Maximum	
Functional	11.67	7.06	4	31	10.67	5.51	2	24	0.770
Physical	11.00	5.62	2	21	10.80	5.43	4	18	0.813
Emotional	9.33	5.54	2	20	8.73	4.80	2	18	0.900
Total	32.00	16.95	10	71	30.47	14.76	8	60	0.982

Table 8 Operative and postoperative data of group A and group B

Groups	Case number	Amount of CAHA (ml)	Postoperative gap between vocal folds by laryngoscope (same gap/decreased gap/no gap (compensated) or compensated)	Patient satisfaction	Need for another injection
Group A patients	1	0.5	Same gap	No	Yes
	2	1.1	Compensated	Yes	No
	3	0.0	No injection	No	Yes
	4	0.5	Decreased gap	Yes	No
	5	1.2	Compensated	Yes	No
	6	1.3	Compensated	Yes	No
	7	0.7	Decreased gap	Yes	No
	8	0.7	Decreased gap	Yes	No
	9	0.8	Decreased gap	Yes	No
	10	0.0	No injection	No	Yes
	11	1.4	Compensated	Yes	No
	12	1.5	Compensated	Yes	No
	13	0.7	Decreased gap	Yes	No
	14	1.3	Compensated	Yes	No
	15	1.5	Compensated	Yes	No
Group B patients	1	0.8	Decreased gap	Yes	No
	2	0.8	Decreased gap	Yes	No
	3	0.5	Decreased gap	No	No
	4	1.0	Compensated	Yes	No
	5	0.5	Decreased gap	No	No
	6	0.9	Compensated	Yes	No
	7	0.8	Compensated	Yes	No
	8	0.5	Same gap	No	Yes
	9	0.9	Decreased gap	No	Yes
	10	0.9	Compensated	Yes	No
	11	1.2	Compensated	Yes	No
	12	0.6	Decreased gap	No	No
	13	1.0	Compensated	Yes	No
	14	0.5	Same gap	No	Yes
	15	1.2	Compensated	Yes	No

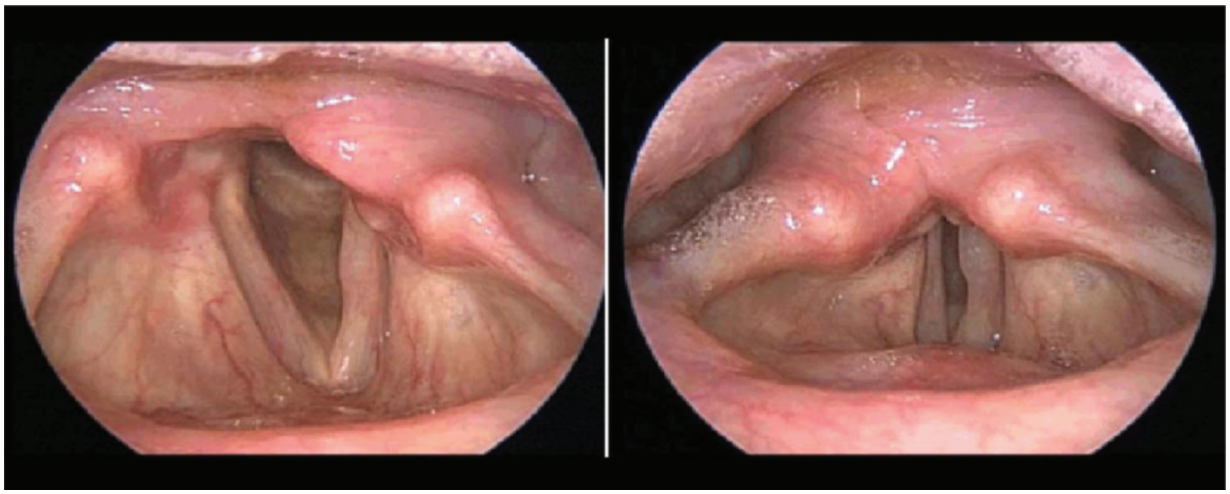
gap/decreased gap/no gap (compensated) or compensated], patient satisfaction, and need for another injection. The amounts used under local anesthesia were more than the amounts used under general anesthesia to close or minimize sizable gaps. Equal number of patients showed full glottic closure with adequate compensation after injection in both groups. Double the number of patients were not satisfied in group B when compared with group A (six and three patients, respectively). In group B, three patients refused re-injection whereas three underwent it; however, in group A, all three patients underwent re-injection (Figs 1 and 2).

Discussion

Otorhinolaryngologists and phoniatricians work hand in hand to achieve best possible functional outcomes after various interventions for voice disorders. They are always in search for quick easily applicable measures to assess quality of life of patients with voice disorders. Arabic VHI can be reliably applied to the Arabic speaking population as it can help in estimating the degree of severity of the voice problem [10].

In this study, causes of UVFP were variable, as 70% were owing to thyroid surgeries, 3% other neck

Figure 1



Laryngoscopic view of vocal folds during phonation and respiration in a patient with unilateral vocal fold paralysis (Phoniatric Unit, Agouza Police Hospital).

Figure 2

In-office injection under local anesthesia (ENT Operating Theater, Office-Based Unit, Kasr El Ainy Hospital).

surgeries, 17% following viral infection, and 10% of idiopathic cause, as shown in results in Table 1. Myssiorek [11] reported in his study in 2004 that thyroid surgery was the most common iatrogenic cause of recurrent laryngeal nerve paralysis; this is in accordance with the etiological profile of the subjects enrolled in this study.

Several studies on patients having UVFP showed variable causes; however, there was a common ground on traumatic and iatrogenic causes, being more common than other causes but with different percentages. In a study conducted by Havas *et al.* [12], they reported that 42% of cases were owing to iatrogenic cause and 30% of idiopathic cause. Another study was published in 2009 by Mehlum *et al.* [13] in which trauma caused 39% of cases and was the most common etiology of UVFP and 27% of cases were of idiopathic cause.

Several parameters were used to measure and compare the functional outcomes and degree of satisfaction such as full history taking, preoperative and postoperative patient interview, laryngeal examination by either flexible or rigid laryngoscopic examination, and voice

assessment including auditory perceptual assessment in addition to VHI, which is the main comparative parameter in this study.

In this study, the females were seen to predominate over males, which indicates that of all 30 patients, 18 (60%) were female patients and 12 (40%) males. This distribution was in agreement with other studies conducted on similar populations. In general, all thyroid disorders are more common in women than in men, whereas some are specific only to women, and this is owing to a hormonal cause [14].

Left vocal fold paralysis was more common than right vocal fold paralysis in the patients under study. Of all the 30 patients, 20 (66.6%) patients have left unilateral vocal fold paralysis (ULVFP) but only 10 (33.3%) patients have right ULVFP. Myssiorek [11] in 2004 explained the high incidence of affection of left side by that the left recurrent laryngeal nerve (RLN) length is 12 cm with long course in mediastinum so that it is in proximity to numerous structures. The diseases or surgeries of these structures can interfere with nerve function by pressure or by disruption.

Objective voice measures and video endoscopic measures for assessment of the voice-related outcomes cannot assess the level of handicap that a patient experiences as a result of his/her voice disorder [15]. The development of VHI allowed patients' subjective feelings regarding their voice disorder to help guide therapist decisions regarding effective voice disorder treatment. VHI is a subjective evaluation based on a patient's own perception and can provide valuable insight into why patients with similar voice disorders experience dissimilar levels of handicap severity [5].

The preoperative VHI scores of group A shown in Table 3 showed that 87% of the patients were severely handicapped regarding their total scores, and 13% were moderately handicapped. Functional domain scores show that 80% of the patients were severely affected and 20% had moderate grade affection. Physical domain scores showed that 87% of the patients had severe grade of physical affection and 13% of the patients had moderate grade. Emotional domain scoring showed that 47% of the patients had mild affection, 6% moderate, and 47% were severely affected. All three domains as well as total scores were severely affected. This is rather expected as the voice plays a major role in the sense of social and physical well-being, and any affection in the voice affects all aspects of life equally.

However, the postoperative VHI scores of group A, as shown in Table 3, show that most of the patients had a reduction in total and subscale VHI scores with marked decrease in the number, severity, and grade of handicap. Postoperative total scores greatly decreased, where 7% of the patients were severely handicapped, 20% of the patients were moderately handicapped, and 73% were minimally handicapped. Functional domain scores showed that 27% were still severely affected and 20% had moderate grade affection, but 53% of the patients became minimally affected. Physical domain scores showed that 33% of the patients still had severe grade of physical affection, 20% of moderate, and 47% of the patients had mild grade affection. Emotional domain scoring shows that 80% of the patients were mildly affected and 20% still had moderate grade of affection.

There was a great improvement in all domains of the VHI as well as total scores. However, as this evaluation was done only one month after injection, a considerable number of patients were still handicapped. Longitudinal studies are therefore needed to assess long-term results of IL on the quality of life of patients receiving it.

The VHI is regarded as the 'gold standard'. It reflects a patient's judgment about the effect of his voice disorder on daily life and can be used as a tool for outcome measurement [16].

The preoperative VHI scores of group B, as shown in Table 4, showed that 87% of the patients were severely handicapped regarding the total scores and 13% were moderately handicapped. Functional domain scores showed that 7% of the patients were mildly affected, 86% severely affected, and 7% had moderate grade affection. Physical domain scores showed that all of patients were of severe grade of physical affection. Emotional domain scores showed that 47% of the patients were of mild affection and 53% were severely affected. UVFP does not only affect the patients' voices, it also affects their functionality, their emotional status as well as their sense of physical well-being. The results of both groups are almost comparable in the preinjection stage. This was taken into consideration so as to fairly judge the postinjection improvement with two approaches under study.

The postoperative VHI scores of group B, as shown in Table 4, show that most of the patients had a reduction in total and subscale scores with marked decrease in the number, severity, and grade of being handicapped.

Postoperative total scores greatly decreased, as 27% of patients with moderate handicap grading became 73% of the patients were of mild handicap and no patients were severely handicapped. Functional domain scores showed that 27% were severely affected, 27% had moderate grade affection, whereas 46% of the patients became minimally affected. Physical domain scores showed that 7% had severe grade of affection, 40% of moderate affection, and 53% of the patients had mild grade affection. Emotional domain scores showed that 87% of the patients had mild grade affection and 13% still had moderate grade of affection. The results were comparable to the results obtained in group A. There was a general improvement in all aspects of the patients' lives. There was still some degree of handicap which could be owing to the technicalities of the procedure itself versus the short duration after injection when this assessment was re-applied.

Bove *et al.* [8] in 2007 reviewed the clinical efficacy of office-based IL compared with operating room-based IL. Their results were in agreement with the results obtained in this study. Both awake and asleep IL showed comparable improvements in VHI scores, and the difference in degree of vocal handicap reduction between both groups was not significant (P=0.882).

Table 5 shows the comparison between preoperative and postoperative VHI score results of group A patients. There was a statistically significant reduction in the postoperative mean values of all domains as well as total VHI scores. The functional mean values reduced from 21 to 11.67, the mean of physical scores reduced from 21.53 to 11, emotional domain mean of scores reduced from 17.53 to 9.33, and the mean of total VHI scores reduced from 60.07 preoperatively to 32 postoperatively. Each VHI parameter showed a statistically significant difference (P<0.0001) when compared with the same parameter before and after the surgery in group A. There is a highly significant reduction in postoperative VHI scores in comparison with the preoperative scores of group A patients. The VHI is considered as a sensitive tool of judging the various degrees of voice handicaps in patients. The results of the current study emphasize this. The degree of the patients' satisfaction went hand in hand with the results of the VHI in the postinjection stage.

Table 6 shows a comparison between the preoperative and postoperative VHI scores of group B patients. It shows a significant reduction in the postoperative mean values of all domains as well as total VHI scores. The functional mean values reduced from 20.27 to 10.67, the mean of physical scores reduced from 22.07 to 10.80, emotional domain mean of scores reduced from 17.8 to 8.73, and the mean of total VHI scores reduced from 60.20 preoperatively to 30.47 postoperatively. Each VHI parameter provided a significant level of reliability (P<0.0001) when compared with the same parameter before and after the surgery in group B, so there is a highly significant difference in postoperative VHI scores in comparison with the preoperative scores of group B patients.

Results obtained in Tables 5 and 6 show that in spite of the different maneuvers used, there was a significant reduction in VHI scores in both groups. It was therefore necessary to compare the degree of improvement to assess and compare the obtained results with the hypothesis suggested at the beginning of the study. This is in agreement with the study by Mathison *et al.* [17] in 2009, which proved that there was no statistical difference in the pre-IL and post-IL regarding the average change in voice-related quality of life scores between the awake and asleep groups.

In today's world, the importance of the role of our voice, in society, is an undisputed fact. It should be put into consideration and kept in mind that treating or restoring a person's voice often changes or restores their complete personality [18].

The results shown in Table 7 compare the postoperative score results of group A and group B. There was no significant difference in the mean values of total VHI scores and subscale scores in the patients of group A postoperatively as compared with postoperative scores of group B, with all P values obtained of more than 0.05. The study by Sulica *et al.* [9]. in 2010 showed similar results, as there was no significant difference in voice outcomes between awake and asleep injection.

The assessment of postoperative glottic gap is a good index of success and expected voice quality after the injection. The better the closure achieved (decrease of the gap), the better the quality of voice obtained, and the more the satisfaction of the patient. Although there were similar results after IL under local anesthesia in the office and under general anesthesia in the operating room, there were some technical and outcome differences noticed between the two procedures.

Selection of patients for the type of the procedure whether under local or general anesthesia depends on the patient agreement, cooperativeness, patient

gag reflex, tolerance to flexible endoscopy, and general state or fitness of the patient. These items should be put in mind before selection of the maneuver, as the patient should be cooperative in office-based procedure to avoid abortion of the procedure.

The results in Table 8 show the comparison of preoperative and postoperative data of group A and group B patients. The comparison was done based on the amount of injectable material used (CaHA) in ml, postoperative gap between vocal folds by flexible nasolaryngoscopy [same gap/decreased gap/no gap (compensated)], patient satisfaction, and the need for another injection. By analyzing the results, it was noticed that the amount used in injection under local anesthesia was more than the amount used under general anesthesia to close or minimize sizable gaps. This can be justified, as there is live feedback from the patient regarding their voice quality and live visual feedback through the endoscopic visualization of the glottic gap; this gives the chance for adequate correction, re-injection, and injection in multiple sites. Moreover, some material could have been wasted in too superficial versus too deep injection, rendering a considerable amount of material lost.Equal number of patients showed full glottic closure with adequate compensation after injection in both groups in this study. Rosen and Simpson [19] in 2010 stated that vocal fold augmentation is used for temporary correction of incompetence owing to UVFP/paresis and permanent correction of mild to moderate glottic insufficiency from soft tissue loss of the vocal fold. This was put into consideration while selecting the patients and their gaps under study.

Double the number of patients were not satisfied in group B when compared with group A (six and three patients, respectively). One of the advantages of in-office injection is that it empowers the patient and makes him/her a decision maker in how much injection is needed to achieve the best quality of voice needed. This affects his/her satisfaction even if not complete compensation is achieved.

In group B, three patients refused re-injection whereas three underwent it, whereas in group A, all three patients underwent re-injection. The idea of undergoing another setting under general anesthesia was not a pleasant or acceptable one to the group B patients, whereas awake in-office second settings was not such a disagreeable idea to the patients who were not fully satisfied in group A.

There was a difficulty to complete the injection in two cases of group A under local anesthesia owing to the high gag reflex, and the two patients were uncooperative during the procedure of injection in the office. This is similar to the results obtained in the study by Mathison *et al*. [17], where six patients of the awake IL had to be either completely or partially aborted. Two of the cases experienced vasovagal reactions, whereas none of the asleep group was aborted.

Upon reviewing all the previously mentioned results, the following conclusion was achieved: voice handicap scoring and the improvement of voice handicap degree of severity in patients after IL under local anesthesia were similar to injection under general anesthesia. The improvement of dysphonia of voice and the degree of satisfaction of voice in patients of both groups were also similar to a great extent. IL cost in the operating room is much higher than office-based procedure, because the patient needs to be admitted in the hospital day before and the day of the surgery, need of full investigation, cost of operating room preparing for surgery, anesthesia and anesthetic doctor cost, preoperative and postoperative nursing cost, and hospital service of patient room such as housekeeping and meals. Office-based procedure saves more time as the procedure takes nearly half an hour in the office, but in the operating room, it needs more time for preparing the patient and the theater, and more time needed for general anesthesia and recovery.

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Conflicts of interest
There are no conflicts of interest.

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