

Objective measurement of real time subglottic pressure during medialization thyroplasty: a feasibility study

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Abstract It is hypothesized that real time objective measurement of the subglottic pressure could contribute to the choice of the implant's size (IS) in medialization thyroplasty (MT). A prospective study was conducted with patients with glottal insufficiency. Patients had a MT using a Montgomery implant® (Boston medical, Boston, USA). Peak direct subglottic pressure (PDSGP) was measured intraoperatively using a catheter inserted in the cricothyroid membrane. The implant's choice was based on the results of PDSGP measured prior and after placement of the implant and was compared to the surgeon's and patient's perception and fiber optic estimation of the glottis aperture. Six patients were included in the first part of the study. The PDSGP could be measured in all the patients without increasing the surgical time or patients'

discomfort. The mean PDSGP before and after the placement of the implant was 15.2 (SD = 5) and 10.6 (SD = 4) cmH₂O, respectively. In the second part of the study, five patients were included. The PDSGP varied with the size of the implant and the implant with the lowest pressure was chosen in 4/5 patients. Peroperative measurement of PDSGP is easy, feasible and might allow a more objective choice of the IS in MT.

Level of evidence 2c

Keywords Medialization thyroplasty · Aerodynamic parameters · Vocal efficiency · Subglottic pressure · Adult

Introduction

Glottal insufficiency (GI) is a cause of breathy voice that can profoundly affect the patient's voice quality. One of the more frequent causes of glottal insufficiency is vocal fold paralysis (VFP); another cause is endoscopic cordecotomy for the treatment of laryngeal cancer of the glottis.

Many options have been introduced for the treatment of GI. They include injection laryngoplasty (IL) [1–3], laryngeal framework surgery [4–7] with or without arytenoid adduction (AA) [8, 9], and laryngeal reinnervation [10]. Type I medialization thyroplasty (MT), a type of approximation laryngoplasty, is the main strategy in laryngeal framework surgery and it has been introduced by Isshiki [4–11].

MT has important benefits. It allows the correction of severe glottal gaps with the preservation of the mucosal wave. However, it is not a perfect procedure and many authors tried to improve the technique by changing the type of the implant: Silastic, hydroxyapatite, titanium, Gore-Tex, Montgomery implant, etc. or by adding arytenoid

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adduction [4–9]. All these implants can be used effectively to treat GI; however, they cannot be modified postoperatively without a revision thyroplasty.

To prevent revision thyroplasty, the surgeon must have adequate tools to choose the appropriate size of the implant during MT and/or the appropriate degree of arytenoid adduction if it is added to the framework surgery. Intraoperative assessment of the adequacy of glottal closure is mostly subjective and based on the perceptual judgment of vocal quality and degree of improvement in glottal gap size as visualized by peroperative fiberoptic laryngoscopy. Only Lundy et al. [12] have introduced the measure of peroperative maximal phonation time (MPT) during MT as an objective mean to predict voice outcome after type I thyroplasty. Maximal phonation time was used alone because other objective measures of vocal quality were considered impractical for use during operative procedures because of the need to keep bulky equipment at a minimum in the operating theater.

The purpose of this study is to assess the feasibility of measuring peak direct subglottic pressure (PDSGP) in the setting of medialization thyroplasty using the Montgomery implant (MI) (Boston Medical Products, Boston, MA) in humans, the variability of PDSGP with the size of the implant (IS) and the impact of the PDSGP in the choice of the IS.

Materials and methods

Subjects

Patients with glottal insufficiency due to vocal fold paralysis or extended cordectomy who were scheduled for MT using the MI, at a tertiary referral center (Otolaryngology Department of Mont Godinne Hospital in Belgium), were included in this prospective study after signing an informed consent. The approval of our institution ethical committee was obtained to perform the study.

Background data including demographic factors (age, sex) etiology of glottal insufficiency (paralysis/cordectomy), and side of paralysis (left vs. right) were obtained from a questionnaire and standard laryngeal examination. All subjects underwent clinical evaluation preoperatively and postoperatively.

Surgical procedure

All subjects underwent MT type I using the MI as described in the article by Montgomery [7]. Surgery was performed under local anesthesia and light sedation. All subjects received intravenous dosages of an opioid for pain control (Remifentanyl). A benzodiazepam (Midazolam) as well as

a short acting hypnotic agent (Propofol) was used for amnesic/anxiolytic effect. A synthetic anticholinergic agent (Glycopyrrolate) was used to decrease salivary secretion. Local injection (subcutaneous and intratracheal) of analgesic (lidocaine 1%, epinephrine 1/200000) was used as needed to control pain. In addition, antibiotics and corticosteroids were given to all patients just before surgery.

Perceptual assessment

The breathy vocal quality was assessed subjectively by the operating surgeon and the speech pathologist after asking the patient to sustain the vowel /a/ at a comfortable pitch and amplitude. Each time the implant model size was changed and the patient was asked to repeat the vowel /a/ three times.

Glottal closure assessment

Glottal closure was also assessed intraoperatively, toward the end of the procedure, when the size of the Montgomery models was changed. An assistant introduced a flexible videoendoscope ENF type VT-2 (Olympus, Lake Success, NY, USA) into the nasal cavity down to the supraglottis allowing real time visualization of the glottal area during phonation. Judgment of glottal closure by looking at vocal folds edge apposition was subjectively made by the operating surgeon each time the implant model size.

Real time peak subglottic pressure measurement

Intraoperative PDSGP was measured in the supine position. After surgical exposure of the thyroid laminae, the cricothyroid membrane was individualized. A large peripheral

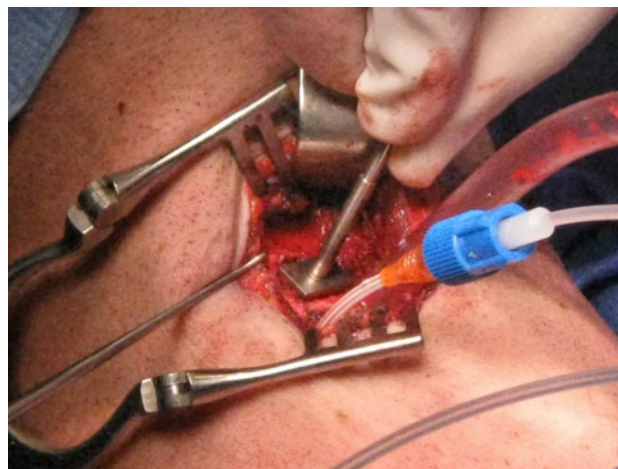


Fig. 1 Direct peak subglottic pressure measure through a catheter inserted into the cricothyroid membrane

venous flexible catheter of 18 GA (BD INSYTE-WTM, NJ, USA) was inserted through the cricothyroid membrane in a sterile manner (Fig. 1). It was connected to the oral pressure sensor of the Phonatory Aerodynamic System (PAS, Kay-Pentax, USA) with a perfusion cable. Care was taken to assure that the sites of connections of the tube were tight. The PAS was managed by the same speech pathologist for all the procedures. The patient was asked to sustain the vowel /a/ three times for each implant size at a comfortable pitch and intensity, the mean value of the PDSGP was recorded. Values were recorded before the creation of the thyroplasty window, and with each size of the Montgomery implant model. The final implant size was chosen according to the perceptual judgment of the patient, surgeon and speech pathologist, the assessment of the glottic gap and the value of PDSGP.

To preserve sterile conditions and assure that data were appropriately collected, the computer was manipulated by the speech pathologist.

Statistical analysis

To assess the difference between PDSGP before the beginning of the MT and the PDSGP after the placement of the appropriate implant, a Wilcoxon signed rank test for paired samples was used.

Results

In the first part of this prospective study, we studied the peroperative PDSGP prior and after the insertion of the implant with the appropriate size. Six patients were included: four men and two women. Four had vocal fold paralysis; all had left vocal fold paralysis with the vocal fold in the intermediate position (between paramedian and lateral position). Two had glottal insufficiency 1 year after extended cordectomies. The mean age was 53 years (range 40–63 years). All patients had previous speech therapy without sufficient improvement.

Peak direct subglottic pressure could be performed in all patients. The mean pressure prior to the creation of the

thyroplasty window was 15.2 cmH₂O (standard deviation = 5). The mean pressure after the insertion of the appropriate implant was 10.6 cmH₂O (standard deviation = 4). The difference between PDSGP before the beginning of the MT and the PDSGP after the placement of the appropriate implant using the Wilcoxon signed rank test for paired samples was statistically significant with $p = 0.028$.

None of the patients was bothered by the insertion of the catheter intraoperatively and all were willing to undergo this kind of surgery again.

In the second part of the study, the PDSGP was measured for each implant's size. The results are reported in Table 1. The size of the implant chosen was that with the lowest PDSGP in 4 of the 5 patients. In the last patient, we encountered difficulties in the measurement of the subglottic pressure and we decided to rely on the perceptive evaluation to make our choice.

Discussion

Despite the numerous types of implants used in type I MT, none, until recently, could be easily adjusted postoperatively. Relying on subjective preoperative assessment of the voice quality, less than 50% of the surgeon's could expect postoperative outcomes [12]. This dilemma has two possible solutions: create an implant that can be adjusted post operatively, or assess the voice intraoperatively with more objective tools than the perceptual judgment.

Hoffman et al. [13] recently published a study on an adjustable balloon implant (ABI) for type I thyroplasty that was explored on excised canine larynges on an experimental bench. The ABI is a silicone balloon that can be filled with saline after it is introduced into the larynx via a standard thyroplasty window and stabilized with a metal frame. It is reversible and offers incremental medialization, however this implant is still in the field of research with no human applications and the authors mention some limitations. On the other hand, authors are trying to include objective voice parameters intraoperatively to have the best possible judgment on the voice quality [12, 14]. Among

Table 1 PDSGP according to implant's size

	Implant 6	Implant 7	Implant 8	Implant 9	Implant 10	
♀ 1	10	9.4	7.6	10.1	12	
♀ 2	8.8	9.8	12.1	NT	NT	
♀ 3	10.9	11.9	16.24	NT	NT	
	Implant 8	Implant 9	Implant 10	Implant 11	Implant 12	Implant 13
♂ 1	25.4	21.0	22.5	14.4	27.5	NT
♂ 2	21.8	16.7	23	20.6	20.2	19.3

Bold denotes the PDSGP of the chosen implant

♀, woman; ♂, man

NT not tested

objective voice parameters, acoustic and aerodynamic parameters can be considered. We wanted to choose a parameter that can be measured easily and that has been linked to vocal efficiency. The subglottic pressure is one of the aerodynamic parameters that have been proposed for voice evaluation [15]. Several authors showed that SGP was statistically higher in dysphonic patients than in healthy subjects [16–19].

The drawbacks of direct subglottic pressure measurement are as follows: It is invasive, in the outpatient setting because of the pressure transducer that has to be placed through the cricothyroid membrane by a puncture. It needs a bulky material. In the surgical setting of type I MT where the patient is sedated and local anesthesia is added, the invasive nature of the placement of the transducer does not apply. For the bulky material, the use of the Phonatory Aerodynamic System (PAS, KayPentax, USA) connected to a laptop can resolve the problem.

In our sample, patients did not report any adverse effect from the measurement, and we could move the Phonatory Aerodynamic System easily from the speech therapy department to the operating room, once a week to operate all the patients needing thyroplasty.

We performed the measurement on a sustained /a/ because it was a direct measure precluding the necessity to use the traditional /pi/ that allows the equalization of oral and subglottic pressure when using Smitheran and Hixon's a non-invasive, indirect method for measurement of SGP: "The airway interrupted method" [20].

We used peak subglottic pressure, because according to Ketelslagers et al. [21], under normal pitch and intensity conditions, there is a significant difference of the peak SGP between patients with vocal fold pathology and controls. This is not true for the mean subglottic pressure.

The mean of the peak subglottic pressure in our population, prior to the insertion of the optimal implant, was 15.2 cmH₂O, whereas in the dysphonic population of Ketelslagers et al., it ranged between 10.6 cmH₂O and 14.5 cmH₂O. After the insertion of the optimal implant, the mean of the peak subglottic pressure significantly dropped to 10.6 cmH₂O while the mean peak subglottic pressure in the control group of Ketelslagers et al. [21] was 9.6 cmH₂O. In 4/5 patients, we observed that the subglottic pressure diminished when the glottis area was reduced by the approximation of the vocal fold until an optimal position was reached. After this position, the augmentation of the size on the MI implant produced an increase of the PDSGP. In one patient, the measures were difficult to obtain, probably because of some difficulties in maintaining the open tip of the catheter in the subglottis and not against the tracheal wall or because the lumen of the catheter was partially obstructed by secretions.

Our study has limitation that will be addressed in the future. The number of patients included is limited, this is why larger studies are needed.

Direct peak subglottic pressure was measured in the supine position under sedation. This could modify its value according to the pre/postoperative measures. However, according to our available data of preoperative estimated subglottic pressure, there does not seem to be an influence of the position and sedation. This finding is in accordance with that of Lundy et al. [12] for MPT.

DPSGP was used as an aerodynamic parameter, however, since its measure was possible, we could probably rely, in the future, on real time vocal efficiency that is the ratio of acoustic power to aerodynamic power and represents the efficiency with which the larynx converts air to sound. It was not used before because the most challenging aspect of calculating vocal efficiency was determining subglottal pressure [22].

Conclusion

Peroperative measurement of DPSGP is feasible and it does not induce patient-related side effects. The use of the PSA did not seem inconvenient or bulky. At present time, this measure is used in combination with perceptive judgment and the visualization of the glottal gap to choose the IS in MT. A prospective multicentric study will allow us to verify the reproducibility of the technique and test it on a larger number of patients.

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Conflict of interest None.

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