

Can Vocal Therapy With Transcutaneous Electrical Nerve Stimulation (TENS) Followed by Vocal Exercises Reduce Benign Laryngeal Lesions in Dysphonic Women?: Randomized, Blind Clinical Trial

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Summary: Purpose: To investigate the effectiveness of vocal therapy with the use of low-frequency transcutaneous electrical nerve stimulation (TENS) followed by voice exercises on vocal fold lesion size, vocal quality and quality of life in dysphonic women. Methods: 27 women with vocal nodules participated, randomized into to: experimental group (EG)—13 women who received vocal therapy with 12 sessions of 20 min of TENS application (pulse:200 μ s, frequency:10Hz, motor threshold intensity, electrodes positioned in the trapezius muscle [descending fibers and submandibular region, bilaterally]). Each TENS session was followed by 30 min of vocal exercises; and the Control Group (CG)- 14 women who received 12 sessions with 20 min of application of placebo TENS (same conditions EG, but without receiving the stimulus electric), followed by 30 min of vocal exercise. Before, immediately after and one month after vocal therapy, participants underwent vocal recording for acoustic analysis, vocal self-assessment, laryngological examination and answered voice-related quality of life (V-RQOL) protocol. Results: There was reduction in the size of vocal fold lesions only in the EG, immediately after treatment and one month after treatment. Acoustic analysis showed decreases in SPI values immediately after and one month after treatment in both groups. There was improvement in voice self-perception in both groups after treatment and one month after, but no significant difference in V-RQOL values. Conclusion: TENS followed by vocal exercises produced results similar to vocal therapy without TENS regarding voice quality, self-perception and quality of life in voice. However, vocal therapy with low-frequency TENS followed by vocal exercise was effective in reducing vocal fold lesion size in dysphonic women.

Keywords: Voice—Voice disorders—Vocal training—Transcutaneous electric nerve stimulation.

INTRODUCTION

Behavioral dysphonia is characterized by a series of vocal, muscular, and laryngeal changes caused by inefficient vocal use behaviors.¹ Excessive muscle tension in the muscles of the laryngeal, cervical, and shoulder girdle regions during phonation is one of the etiologies of this type of dysphonia, which generates different adjustments in the vocal tract and symptoms of musculoskeletal pain.²

It is known that the laryngeal configuration in women facilitates the appearance of incomplete glottal closure, with medium-posterior, triangular and hourglass shaped, with a triangular component types most commonly observed.^{3,4} When associated with the inefficient use of the voice (loud vocal use, excessive vocal effort, muscle tension; etc), this incomplete closure generates greater friction in the mid-posterior region of the vocal folds, reducing the anteroposterior

space of the larynx and leading to the appearance of benign lesions, such as bilateral vocal nodules or contralateral nodular reaction to minimal structural alteration.⁵⁻⁷

Due to the characteristics of musculoskeletal tension associated with behavioral dysphonia, electrical stimulation has been considered in recent years as an adjunctive therapeutic resource in the treatment of vocal and laryngeal disorders for this type of dysphonia.⁸⁻¹³ There are several types of electric currents that have specific therapeutic goals depending on the choice of physical parameters that will compose the current, such as frequency, intensity, and pulse duration. The configuration of these parameters may stimulate afferent fibers (sensory, generating, for example, paresthesia) or efferent fibers (motor, promoting muscle contractions), or even nociceptive fibers, causing pain in the stimulated region.¹⁴ In addition, the type of electrode material and its position in the laryngeal region and surrounding areas also influence the type of stimulus applied.¹¹

Some studies in the voice area are aimed at investigating the effects of neuromuscular currents (NMES) in the treatment of paralysis,^{15,16} vocal fold bowing¹⁷ and even in vocally healthy individuals,^{18,19} since such current stimulates motor fibers providing more vigorous muscle contractions. The authors of these studies observed that this therapeutic resource enabled improvement in vocal quality, vocal fold movement, quality of life, and decreased mass

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injury. However, there is divergence as to the nomenclature of the electric current used, with small samples and methodologies with low levels of evidence, since most research is composed of case studies.

On the other hand, studies^{8–10,13,20,21} in recent years have investigated the effects of applying another type of electrical current called transcutaneous electrical nerve stimulation (TENS). The TENS current is based on the Theory of Gates,²² inhibiting nociceptive fibers, stimulating sensory fibers, and/or releasing endogenous opioids²³ for pain management. This low-frequency current has been used to provide muscle relaxation in proximal areas of the larynx and neck, reducing the frequency and intensity of musculoskeletal pain, through stimulation of sensory and motor fibers, and improving vocal quality in behavioral dysphonia.^{8,9,12}

TENS with electrodes placed in the submandibular region and trapezius descending fibers, with low frequency and strong intensity in the motor threshold, promote rhythmic muscle contractions of the stimulated musculature, with consequent shaking in the larynx.^{9,11} These contractions can increase blood flow, favoring the drainage of metabolites, which allows muscle relaxation and, consequently, a decrease in musculoskeletal pain.¹⁴ This is because this type of application of electrical stimulation, in addition to the physical parameters of the current, is based on the placement of electrodes: an electrical stimulation channel on each side, which generates two electric fields, right and left, with greater interelectrode distance.¹² In this way, more structures are stimulated, favoring a shaking of all the larynx. If the electric field of electrostimulation application were restricted to a channel in the submandibular region and another in the trapezius muscles, the electrodes would have a smaller distance, and the stimulation would be limited to these regions, with less density and depth. That is, the effect of electrostimulation may be different, but there are still no studies in the area of voice that have investigated whether there are differences in effectiveness in the different types of electrode placement. Therefore, it is noteworthy that depending on the interelectrode distance, location of the electric field, amount of water in the applied tissue, number of layers of the stimulated structures, as well as the physical parameters that make up the current, the current impedance may increase or decrease under the skin and thus modify the biological responses.²⁴

Most studies using a TENS current, focusing on the application to improve voice and laryngeal function, have sought to verify the immediate effects of electrical stimulation alone or only combined with vocal exercise.^{10,20,25} Four studies were found that investigated the effects of low-frequency TENS over a 10- or 12-session treatment.^{8,9,12,13,21} Only two of them associated electrical stimulation with vocal therapy.^{12,21} Both observed positive effects on vocal quality, either in auditory-perceptual analysis or acoustics, and reduction of musculoskeletal pain. However, a single study showed follow-up of effects on individuals after its application regarding musculoskeletal pain and trapezius muscle pressure threshold, finding that TENS

combined with vocal therapy is effective in reducing pain in dysphonic women.¹² However, it is still necessary to investigate the effectiveness of voice therapy combined with low-frequency TENS, on vocal quality and laryngeal structures, to better understand the effects of TENS in clinical practice.

In general, the panorama of voice research involving this theme reveals an increase in studies with good levels of evidence. However, it is necessary to understand more broadly and in-depth the applicability and effects of low-frequency TENS associated with vocal treatment in the voices and larynxes of dysphonic individuals in the medium term. Thus, this study aimed to investigate the effectiveness of vocal therapy with low-frequency TENS followed by vocal exercises on vocal quality, quality of life, and vocal folds lesion size in dysphonic women.

METHODS

Design and ethical aspects

This randomized, double-blind clinical trial was carried out using the PICO strategy (**P**opulation—women with vocal nodules; **I**ntervention—TENS application associated with vocal therapy; **C**omparison—TENS placebo associated with vocal therapy; **O**utcomes—vocal quality, quality of life, and laryngeal aspects) following the recommendations of CONSORT,^{26,27} according to the publication of the previous study.¹² The study was approved by the research ethics committee of the institution under number 556.273 and is registered on the REBEC platform as a clinical trial (register number: RBR-3z3d6). All participants signed an informed consent form.

Professionals

The present clinical trial was conducted by a research group to enable the masking of research steps and the impartiality of the data. The tasks and masking of the professionals were carried out as follows:

- Professional 1 was a speech-language pathologist responsible for the randomization of participants and their allocation to the intervention groups. The professional was blinded in relation to the other stages of the research (evaluation and treatment of research participants and analysis of treatment data).
- Professional 2 was a speech-language pathologist responsible for the selection of the sample and evaluation of the outcome variables. This professional was responsible for the application of the low-frequency TENS or placebo and was blinded regarding randomization of the sample. Only this professional knew what treatment each participant received.
- Professional 3 was a speech-language pathologist responsible for the application of vocal therapy and for editing the materials regarding outcome variables for statistical analysis. This professional was blinded in relation to the selection and randomization of the

sample, the collection of outcome variables, and the type of electrostimulation (TENS or placebo).

Sample

The sample size was calculated in a pilot study with 10 women with vocal nodules and voice complaints (5 women in each group), who also participated in the main study. The largest standard deviation found for the difference between two means of dependent groups was used as an estimate of variability (19.42 mm on the analog visual scale). We adopted a level of significance of 0.05 ($\alpha = 5\%$) and 80% test power ($\beta = 80\%$) to detect a minimum difference between groups equal to one standard deviation. Thus, the sample size required was at least 12 participants in each group, considering a loss of 20% of the sample during data collection.

Inclusion criteria were female gender, age between 18 and 45 years old, report of current complaint of vocal alteration or altered voice evidenced by a speech-language auditory perceptual assessment, bilateral vocal nodules or mucous membrane edema, and incomplete glottic closure, evidenced by otorhinolaryngological evaluation.

We excluded all participants who reported receiving previous speech therapy, who reported any neurological changes, thyroid gland changes, who had undergone clinical treatment for hormonal control (except contraceptive pills), vocal or surgical laryngeal treatment, menopause, heart disease, high blood pressure, hyper- or hypothyroidism even if clinically controlled, smokers and drinkers, and participants who had already used TENS for some type of treatment.

After applying the selection criteria, 27 women with behavioral dysphonia were selected to participate in the study. To generate the randomized sample allocation sequence, numbering from 1 to 27 was performed prior to the beginning of the procedures in a Microsoft Office Excel 2007[®] spreadsheet. The number distribution was performed in two groups the experimental group (EG) and the control group (CG). Using the “random between” function, the program randomized the sequence of numbers. These were allocated in sealed envelopes, and from the first therapy session of each participant, the envelope draw defined which group the participant would be part of. The randomization of the sample was simple, occurring in two blocks due to the complementation of the sample after the pilot study.

Thus, the participants were allocated into two groups: EG—13 women with behavioral dysphonia who received vocal therapy with low-frequency TENS followed by guidance and vocal exercises, and CG—14 women with behavioral dysphonia who received vocal therapy with placebo TENS followed by vocal guidance and exercises.

Outcomes

All participants were assessed according to vocal fold lesion size and glottic closure, acoustic analysis, voice-related quality of life and vocal self-assessment. All evaluations were performed at three times: before the intervention

(Before), immediately after the intervention (After), and one month after the end of the intervention (After1).

Vocal fold mass lesion size and glottic closure

The laryngeal examination consisted of the stroboscopic tele-laryngoscopy, performed by a single otorhinolaryngologist in the presence of Professional 2, who asked the participants to perform phonatory tests to analyze the laryngeal behavior during phonation.

For tele-laryngoscopy, a Panasonic GP KS152 70° rigid fiber optic was used, and for stroboscopy, as well as an Endo-Strobe rhino-laryngeal stroboscope (RLS 91003 from Kay Elemetrics). The light source used was a 250 W halogen bulb from Ferrari Medical. Images of the laryngeal structures were captured by an Olympus Medical Systems Corp. ENF Type P4 digital color microcamera and transmitted to a Sony LMD 1420 LCD video monitor. These exams were recorded by the Philips Model 3455H DVD player and later stored on a DVD. During the examination, the participants remained with their heads towards the body axis, without flexion or rotation. Optical fiber was introduced through one of the nostrils and middle meatus up to the larynx region, allowing ample supraglottic and vocal fold vision. Such procedures were adopted to minimize biases in the placement of the endoscope at different moments of evaluation.

Laryngeal structures were analyzed during habitual breathing, vowel / i / emission in the usual way and with frequency variation, as well as inspired vowel / i / emission and number counting, by an otorhinolaryngologist. The emission of the vowel /i/ was chosen for this evaluation because it allows a better visualization of the structures and functioning of the laryngeal structures during phonation.

The laryngeal images were later edited and analyzed by a speech-language pathologist (voice specialist for over 20 years) who was an independent evaluator of the research procedures, comparing them blindly and in a paired way. For visual-perceptual analysis of the size of the lesion and glottic closure, photographs of the video recordings (laryngeal examination) of the vocal folds in adduction during the emission of the vowel /i/ and abduction of each participant were captured, in an overhead and centralized view (Fig. 1). The judge indicated whether appearance increased, decreased, or presented no difference^{10,28} as to vocal fold lesion size and glottic closure.

Acoustic analysis

Acoustic analysis was performed from recordings of the vowel / a / emission. Participants remained comfortably seated in a chair within an acoustically treated room and were instructed to emit the vowel / a / in a sustained manner at their usual pitch and loudness. The emission was captured by an AKG Model C 444 PP microphone (AKG Acoustics GmbH, Vienna, Austria) positioned at 45 degrees in front of the mouth, four centimeters away from the lip commissure. The recording was performed directly on a system

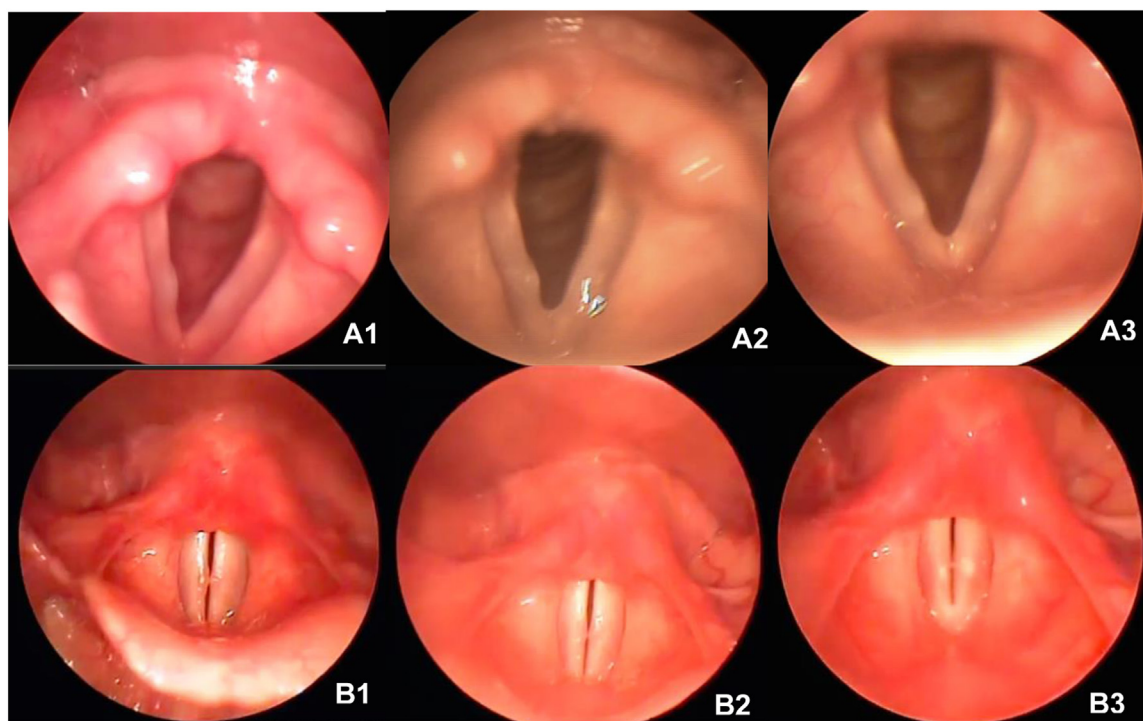


FIGURE 1. Laryngeal images in abduction (A) and in adduction (B) in the moments before the intervention (1), immediately after the intervention (2) and one month after the end of the intervention (3). The images are from the same participant.

consisting of an Intel Pentium 4® computer, 2,040 GHz CPU and 256 MB RAM, LG Flatron E7015 17 monitor, Audigy II sound card (Creative Technology Ltd, Singapore), and Sound Forge 10.0® Professional Audio Editing System software (Sony Creative Software Inc., USA), at a 44,100Hz sampling rate, into a 16-bit mono channel.

Using Sound Forge 10.0® software, the recordings were edited by selecting the best excerpt of the vowel / a / emission. The beginnings and ends of the broadcasts were discarded in order to eliminate the main parts of vocal instability. Acoustic parameters were extracted using the Multi-Dimensional Voice Program (MDVP) model 5105 (Kay Elemetrics Corporation, USA). The following parameters were extracted: fundamental frequency (f_0), standard deviation of f_0 (SD f_0), peak-to-peak amplitude variation (vAm), frequency variation (vF0), vocal turbulence index (VTI), soft phonation index (SPI) and noise-harmonic ratio (NHR). These acoustic measures were chosen because they can provide information on glottic closure in a non-invasive way, contributing to the understanding of vocal noise,²⁹ mainly for therapeutic follow-up.

Voice-related quality of life

The Voice Quality of Life (V-RQOL) protocol consists of 10 questions and three domains (physical, socio-emotional and total).³⁰ Participants answer each question on a scale ranging from one (not a problem) to five (a very large problem). The calculation of each domain was performed as proposed by the authors.³⁰ The value of each protocol domain ranges from 0 to 100%; the closer to 100%, the better the voice-

related quality of life. A translated and validated version for Brazilian Portuguese was applied.³¹

Voice self-assessment

Participants were asked about self-rated voice quality on a scale of 1 to 5, with “1” representing excellent voice self-perception, “2” very good voice, “3” good voice, “4” a reasonable voice and “5” a bad voice.

Vocal therapy

Twelve vocal therapy sessions were held twice a week, lasting approximately 50 min each. To control treatment, it was established that participants could not have more than three consecutive absences and that all absences would be rescheduled. Each session was divided into two parts:

- 1) TENS application: application of low-frequency TENS lasting 20 min. EG participants received TENS, and CG participants received TENS placebo.
- 2) Shortly after TENS application, the second part of each session consisted of vocal orientations and exercises applied equally to the EG and CG. Each session lasted approximately 30 min.

TENS application

The equipment used for the application of TENS was the Quark brand Dualpex 961® using two channels. The physical parameters of the TENS current used were symmetrical biphasic quadratic pulse, 200 μ s pulse width, 10 Hz

frequency and motor threshold intensity (stimulating efferent fibers, which proves rhythmic muscle contractions). To decrease the impedance of conduction of electrical stimulation, the skin was cleaned with gauze and alcohol gel in the submandibular region and the trapezius muscle descending fibers, bilaterally. After cleaning, four carbon electrodes ($3 \times 5\text{cm}$) greased with electroconductive gel and fixed to the skin with anti-allergenic tape were placed over the pain areas of the aforementioned muscle groups, according to a study by Silverio *et al.*⁹. Two electrodes of the first channel were placed on the right side, and two electrodes of the second channel were placed on the left side.^{9,12} TENS was applied to all participants in the supine position on a portable stretcher. Participants were instructed to remain at rest and not to vocalize.

In the EG, the stimulus intensity was increased during the first 10 min until rhythmic muscle contraction (similar to fibrillations) was observed visually in the submandibular and descending trapezius fibers muscle regions. The increase in intensity was performed according to individual sensitivity comfortable for the participants. For the next 10 min, the stimulation intensity remained constant. The application of the electrodes and positioning of participants to perform the placebo TENS in the CG were the same procedures as for the EG; however, the equipment did not emit an electrical current.

Behavioral dysphonia therapy program: voice guidance and exercise

The behavioral dysphonia therapy program (BDTP) applied in this study was developed and published in a previous study¹². The program's therapeutic objectives were to raise awareness about the laryngeal and vocal alterations found in the evaluations, advise on vocal health, relax the cervical muscles, soften the emission, mobilize the mucosa, promote complete glottic closure, balance resonance and articulatory patterns, improve pneumophonoarticulatory coordination and communicative competence (transfer of new vocal behaviors to real communication situations). The following exercises were used: Stretching of the entire body, Laryngeal Manual Therapy, Humming /m/ in usual pitch associated with horizontal head movement; humming /m/ with frequency variation; Vibration of tongue or lip or fricative /v/ with horizontal head movement and/or frequency variation; Overarticulation of speech, Sound-blowing with tube of resonance; chanting voice. The therapy program was performed in 30 min, and each execution of vocal exercises lasted three minutes, with progression across a task hierarchy. BDTP was applied in both groups.

During the one-month follow-up, participants were instructed to perform vocal exercises at home. These were the same exercises given at the last therapy session and were repeated twice a day for one minute each. There was no control by the researchers on whether exercises were performed at home.

Statistical analysis

The Shapiro-Wilk test was used to verify the normality of the data and then a two-way repeated-measures ANOVA test was applied for comparisons between the three assessment moments of both groups concerning acoustic measurements and the V-RQOL protocol. In situations where the ANOVA test showed a significant difference for the variables time or therapy or therapy versus time, a Tukey test was applied to verify in which groups and moments such changes occurred. For the vocal self-assessment variable, Kendall's W test was applied. For laryngeal structures, we used the sign test for intragroup analysis and likelihood ratio test for intergroup analysis.

Statistical analysis was performed using Statistica software version 17.0 ($p < 0.05$).

As for the power of the study, the data indicated that the rate of worsening in the CG was 0.455. If the true rate for the EG sampling elements is 0.273, it is possible to reject the null hypothesis that the worsening rates for the EG and CG sampling elements are equal with a power of 76.3%. The type I error associated with this test for this null hypothesis is 5%. An unadjusted chi-square statistic was used.

RESULTS

After applying an initial questionnaire, 53 laryngological examinations were performed in this study. After otorhinolaryngological diagnoses, 27 participants started vocal treatment, but four participants gave up treatment during therapy. Thus, 23 participants completed the treatment, 12 of them from the EG (average age of 29 years; standard deviation of 5.60) and 11 from the CG (average 31.5 years old; standard deviation 8.48). The sample representation in previous study is shown in Fig. 2.

The following are the results for both groups regarding the different assessment times of pre-treatment (Before), immediately after treatment (After) and one month after treatment (After1).

Figs. 3 and 4 show the results of intra- and intergroup comparisons regarding the analysis of laryngeal images in the three evaluation moments performed by the judge. Intra-rater agreement was performed using the kappa test, which was excellent for all parameters evaluated, with a percentage of agreement ranging from 83.33 to 91.67.³² There was a difference between the different evaluation times for the lesion size parameter only in the EG.

Table 1 shows the statistical results of the acoustic parameters of the voices of the EG and CG at the different times of evaluation. Only the parameter SPI presented lower values at the times after treatment in both groups. There was a difference between the groups regarding the VTI parameter, which was significantly higher for the CG.

Table 2 shows the results regarding the V-RQOL protocol at the different assessment times in both groups. It was possible to verify that there were no changes in voice-related quality of life after treatment for either group at different evaluation times.

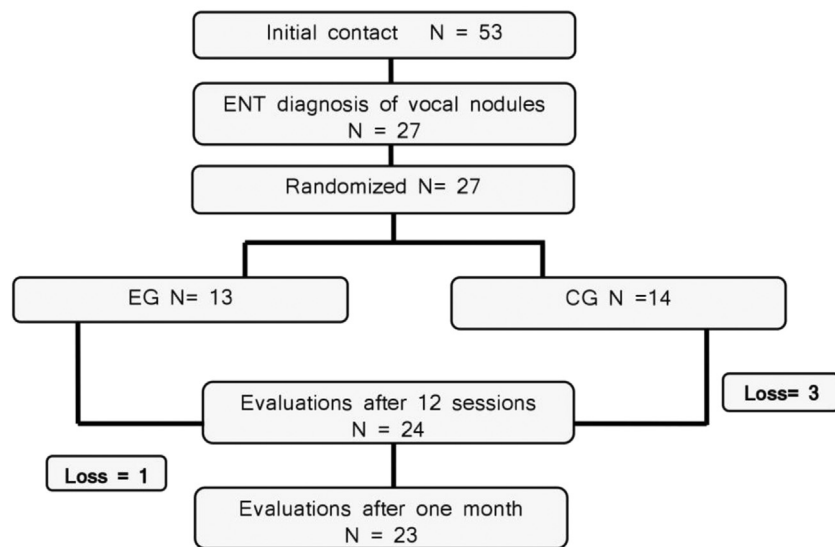


FIGURE 2. Flowchart referring to the research steps in relation to the study sample.

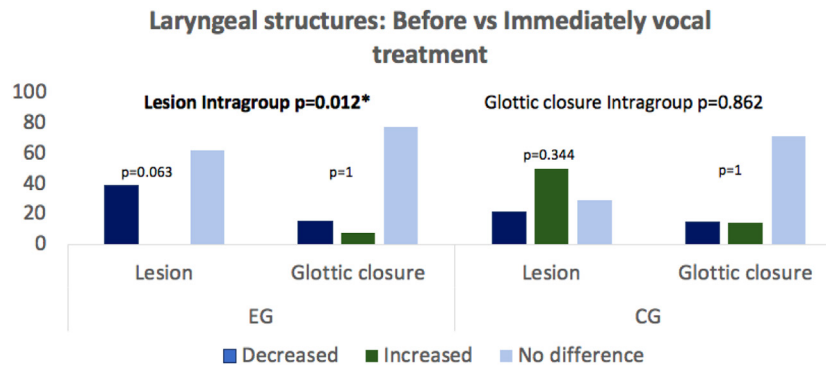


FIGURE 3. Comparison between experimental (EG) and control (CG) groups according to the results obtained in the visual perceptual judgment between the moments before and after immediate treatment.

Table 3 shows the data regarding vocal quality self-assessment by category, frequency and percentage of both groups. No difference was observed among the different evaluation times in the EG, and the voice classifications were “good” and “reasonable.” For the CG, a significant difference was noted between the evaluation times: participants self-rated their voices as being “good” immediately after treatment and “reasonable” after one month of treatment.

DISCUSSION

The type of TENS current used in the present study seeks to relax the cervical and laryngeal muscles, promoting shaking of all the larynx. This is due to the choice of current based on its frequency and amplitude, as well as the placement of electrodes. This study follows the principles recommended by the literature:^{8,9,12} low frequency at 10Hz, pulse width at 200 μ s, strong intensity at motor threshold, with positioning of the electrodes on the submandibular region and pain area (point of greatest muscle stiffness) the descending fibers of the trapezius muscle. The four electrodes in this study were

silicone-carbon type, a material that offers lower resistance and better conductivity of the electric current, with a size of three centimeters by five centimeters. Electrodes were positioned at the point of greatest muscle stiffness to generate a better motor response with less painful stimulus.¹⁴ The configuration of the electrode placement selected in each channel provided strong passive mechanical vibration of the larynx and trapezius muscle due to rhythmic muscle contractions, causing possible muscle relaxation.¹¹ The application of TENS was performed with the participants in a supine position to provide greater comfort and better stimulation in the submandibular region and descending fibers of the trapezius.

Regarding the speech therapy treatment of behavioral dysphonia specifically, the several studies have investigated the effects of vocal therapies with varied therapeutic approaches.^{33–41} Among them, only three studies were randomized controlled trials that conducted six to eight vocal treatment sessions.^{36,37,41} One of these three studies was chosen as a form of vocal treatment from clinical trials to evaluate the effectiveness of TENS followed by vocal

TABLE 1.
Mean and Standard Deviation of the Acoustic Parameters of the Experimental (EG) and Control (CG) Groups, at the Different Evaluation Moments: Pre-Treatment (Before), Immediate Post-Treatment (After) and After one Month of Treatment (After1).

Parameters	Before		After		After		Anova		Tukey
	EG (Mean ± SD)	CG (Mean ± SD)	EG (Mean ± SD)	CG (Mean ± SD)	EG (Mean ± SD)	CG (Mean ± SD)	Effect	P	
F₀	194.98 ± 15.95	186.82 ± 21.42	201.16 ± 21.22	190.63 ± 19.24	200.84 ± 22.23	189.74 ± 21.30	Group Moment Moment x Group	0.143 0.345 0.915	
Dp F₀	3.504 ± 1.58	4.752 ± 6.34	3.44 ± 0.96	3.371 ± 1.56	3.163 ± 1.23	2.981 ± 1.16	Group Moment Moment x Group	0.655 0.342 0.555	
VAm	12.272 ± 8.57	11.944 ± 8.39	13.789 ± 11.61	10.543 ± 4.09	13.779 ± 9.60	11.131 ± 3.58	Group Moment Moment x Group	0.413 0.974 0.638	
VTI	0.031 ± 0.01	0.04 ± 0.02	0.034 ± 0.01	0.04 ± 0.01	0.036 ± 0.01	0.039 ± 0.01	Group Moment Moment x Group	0.023* 0.663 0.571	CG>EG
SPI	18.238 ± 9.03	20.383 ± 12.26	13.19 ± 8.88	14.39 ± 9.67	13.969 ± 7.08	14.131 ± 8.41	Group Moment Moment x Group	0.709 0.002* 0.831	After, After 1<Before
NHR	0.111 ± 0.03	0.123 ± 0.04	0.125 ± 0.03	0.137 ± 0.03	0.133 ± 0.03	0.136 ± 0.02	Group Moment Moment x Group	0.22 0.083 0.818	

* ANOVA of two repeated measurement criteria and Tukey ($p \leq 0.05$) Caption: f₀: fundamental frequency; SD f₀: standard deviation of fundamental frequency; NHR: noise-harmonic ratio; Vf₀: frequency variation; vAm: amplitude variation; SPI: soft phonation index; VTI: vocal turbulence index. Moment = intragroup evaluation; Group = intergroup evaluation; Moment vs. Group = intra and intergroup evaluations.

TABLE 2.
Voice Quality of Life Protocol (V-RQOL) Values, as a Percentage, in the Experimental Group and Control at the Different Evaluation Times: Pre-Treatment (Before), Immediate Post-Treatment (After) and After one Month of Treatment (After1).

Domains	Before		After		After1		Anova	
	EG (Mean ± SD)	CG (Mean ± SD)	EG (Mean ± SD)	CG (Mean ± SD)	EG (Mean ± SD)	CG (Mean ± SD)	Effect	p
V-RQOL SE	68.77 ± 29.08	76.81 ± 29.25	75.02 ± 30.08	84.39 ± 15.64	75.98 ± 34.96	75.46 ± 26.10	Group Moment Moment x Group	0.574 0.191 0.367
V-RQOL Physical	62.50 ± 28.47	57.44 ± 30.06	70.50 ± 25.43	61.02 ± 30.06	72.76 ± 21.58	59 ± 24.66	Group Moment Moment x Group	0.283 0.257 0.564
V-RQOL Total	65.38 ± 25.22	65.18 ± 27.41	72.31 ± 25.24	70.36 ± 17.92	74.42 ± 24.28	64.46 ± 23.64	Group Moment Moment x Group	0.628 0.257 0.381

*ANOVA of two repeated measurement criteria and Tukey ($p \leq 0.05$) Caption: OOL: Voice Quality of Life; Caption: Moment = intragroup assessment; Group = intergroup evaluation; Moment vs. group = intra and intergroup evaluations.

therapy.⁴¹ Regarding TENS, the literature recommends application between 10 and 12 sessions.^{8,9} Thus, we chose to perform vocal therapy in 12 sessions¹² based on the objectives and exercises recommended by the Comprehensive Voice Rehabilitation Program (CVRP).⁴¹

The therapy program proposed here is based on the patient learning how to develop more appropriate vocal behaviors.^{12,41} In addition, participants should practice the recommended exercises from each therapy session daily to avoid the principle of exercise physiology called reversibility.⁴² That is, daily practice should maintain the gains from therapy.

Regarding the comparison of laryngeal images between the evaluation moments, the EG was statistically better than the CG in relation to the size of vocal fold mucosa lesions immediately after and one month after treatment (Figs. 2 and 3). This fact can be understood from the way vocal therapy was developed in the EG, with the application of TENS followed by vocal exercises. The physical parameters selected for TENS, together with the placement of the electrodes in the submandibular region and in the descending trapezius fibers musculature, provide a strong passive mechanical vibration in the laryngeal and perilaryngeal region due to muscle contractions caused by this current.¹¹ This stimulation for 20 min over the 12 treatment sessions is also capable of generating strong vocal fold vibrations because it provides a “laryngeal shake”.⁹ Consequently, it can be assumed that, although without phonation, TENS redistributed muscle strength and mobilized the vocal fold mucosa, favoring the reduction of edema in the vocal folds. It is important to emphasize that this type of electric current has the therapeutic objective to improve drainage at the application site. This fact associated with vocal therapy sessions caused the reduction of the lesions, indicating softer phonation as perceived by the reduction of the lesion size and lower SPI parameter values (Table 1).

Santos et al.¹⁰ observed that after the application of low-frequency TENS, concomitantly or not with tongue vibration, there was an immediate improvement in the glottic closure of women with vocal nodules, which was not found in this study after 12 TENS sessions followed by vocal therapy. No other studies were found on laryngeal behavior after TENS current application.

The literature shows more clearly studies that used other types of electrical currents such as NMES in the treatment of various vocal and laryngeal alterations, such as vocal folds bowing¹⁷ and vocal fold paralysis dysphonia.^{16,43} In these studies, an improvement in glottal closure and vocal fold mucosal waves were found. However, the authors recommended that more controlled and randomized studies be performed to verify the effectiveness of this resource, since the effects were mostly found in case reports.^{16,17,43}

As previously reported, no significant changes were confirmed for the CG regarding any laryngeal aspect in the comparative evaluation of the images. It is noteworthy that immediately after treatment, the vocal fold lesions of the CG increased in 50% of the sample. At one month after,

TABLE 3.

Values of Vocal Self-Perception, by Categories, in Frequency and Percentage, in the Experimental Group and Control in the Different Evaluation Moments: Pre-Treatment (Before), Immediate Post-Treatment (After) and After one Month of Treatment (After1).

Categories	EG				CG			
	Before	After	After 1	P	Before	After	After 1	p
Excellent	0 (0%)	0 (0%)	0 (0%)	0.070	0 (0%)	0 (0%)	0 (0%)	0.013*
Very Good	0 (0%)	1 (7.7%)	0 (0%)		1 (7.1%)	2 (14.3%)	1 (7.1%)	
Good	4 (30.8%)	7 (53.8%)	8 (61.5%)		3 (21.4%)	7 (50%)	3 (21.4%)	
Reasonable	5 (38.5%)	4 (30.8%)	5 (38.5%)		7 (50%)	5 (35.7%)	10 (71.4%)	
Bad	4 (30.8%)	1 (7.7%)	0 (0%)		3 (21.4%)	0 (0%)	0 (0%)	

* Kendall W Statistics Test ($p < 0.05$).

lesions were considered equal to the pre-moment measurement at 71.4%. That is, the visual-perceptual analysis of laryngeal images did not reveal significant reduction after vocal treatment during the proposed period. However, we note that 30 days after the end of treatment, there was an increase of the lesion sizes in the EG, which did not occur in the CG. This may be the result of the electrical stimulation itself: terminating its application without actually treating until the complete disappearance of the lesion in each participant, which may have contributed to the worsening of the gains obtained over the 12 sessions. Another fact that can be attributed to this result is the lack of change in vocal habits. One of the hypotheses raised is that electrical stimulation can give the TENS recipient the feeling that “something besides me (the patient) acts and so I do not strive to change my habits and maintain what has been achieved in therapy.”

There are studies in the literature that investigated the effects of vocal therapy in patients with vocal nodules or with muscle tension dysphonia. Of these studies, only five examined laryngeal physiology on imaging. They observed that after treatment, there was reduction of lesion and glottic closure, in addition to cases in which there was total remission of the lesion without recurrences.⁴⁴ However, it is noteworthy that most of these studies performed vocal treatments for a longer period than that

applied in this study.^{39,45–47} These studies showed differences in the number of sessions performed, ranging from six to 40 vocal treatment sessions.

The present study, based on the CVRP method⁴¹ and the literature on TENS application,^{8,9} was performed in six weeks over 12 sessions, with daily practice twice a week.⁴⁸ Thus, the treatment time of this study may not have been sufficient to promote significant improvement in the laryngeal behavior of women with vocal nodules. Perhaps future studies with longer treatment times may modify this result. Patients with this type of dysphonia need to modify inappropriate vocal behaviors, which requires more time to change their habits and transfer newly learned vocal behaviors to spontaneous speech. It is also suggested that future studies be carried out using more objective and robust methodologies for the analysis of laryngeal images, using computer programs, which can be compared with subjective analyses, as performed in this study. Although the visual-perceptual analysis of the images was reliable, it is noteworthy that it is subjective and can be considered a limitation of this study, since the distance and angle of the endoscope can influence as a confounding factor in the interpretation of the results.

Based on the above, the findings of the present study allow us to conclude that low-frequency TENS with motor

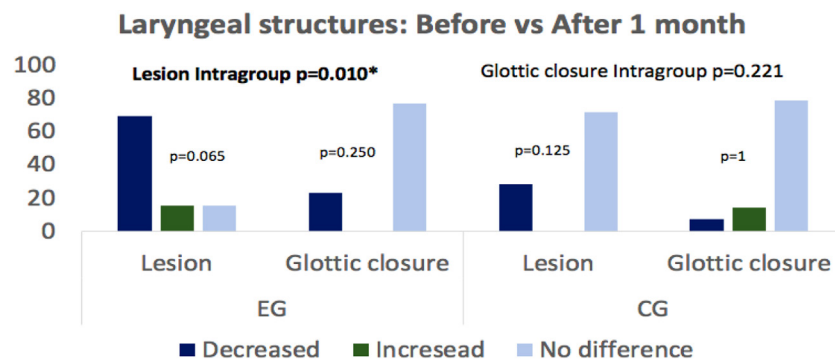


FIGURE 4. Comparison between experimental (EG) and control (CG) groups according to the results obtained in the visual perceptual judgment between the moments before and after one month of treatment.

threshold intensity may be an effective resource to decrease benign vocal nodule-type laryngeal lesions in women. This method was unable to produce many changes in vocal folds, laryngeal behavior, such as improvement of glottic closure during phonation.

Regarding the acoustic analysis showed a significant decrease of SPI values after vocal therapy in both groups, as well as the maintenance of values one month after the proposed treatment. The SPI is a parameter indicative of how smooth the glottal closure is during phonation.⁴⁹ High SPI values may be related to incomplete glottic closure, and studies with dysphonic individuals indicate high SPI values in the presence of laryngeal changes.²⁹

Maintaining SPI values in both groups one month after the proposed treatment may indicate, regardless of the associated use of TENS, that participants were able to maintain glottal closure smoothing during phonation after therapy. Such results may have occurred because both groups received guidance on vocal health and exercises that favor emission softening, vocal fold mucosa mobilization and adequacy of glottal closure. These therapeutic objectives were worked through the application of manual laryngeal therapy, exercises with vibrating, nasal and fricative sounds and their frequency variations, as well as sonorous breath exercises that stimulated better glottic coaptation and greater amplitude of the mucosal wave of the vocal fold muscles. Thus, there may have been an improvement in the softness of the glottal closure, as reflected in lower values of the acoustic parameter SPI. According to certain authors,⁴² the benefits gained from muscle training can be extended with continuous practice. Thus, the improvement maintained one month after vocal treatment is possibly due to the fact that participants continued daily vocal exercises at home along with good vocal behavior.

Studies evaluating the effectiveness of TENS in women with vocal nodules^{8,10,21} reported no significant changes in acoustic parameters after application of this feature. Other studies in the field of voice that used neuromuscular electrical stimulation (NMES or TES) evaluated the effects of these currents in relation to acoustic parameters. Some did not find changes, in the acoustic parameters immediately after a single session of the TES currents in vocally healthy individuals,^{19,50} which corroborates the present study. On the other hand, other studies found that after NMES application, there were reductions in relative sound pressure level,¹⁸ jitter, shimmer and vocal noise measurements.^{16,43}

In the present study, it was observed that the reduction of the SPI acoustic parameter values shows that there was a possible improvement in voice softening. That is, vocal therapy may have contributed to a normotensive approximation of the vocal folds, with a possible improvement in the source and filter interaction,⁵¹ in both groups. Thus, considering vocal quality, it was possible to verify that TENS, when followed by voice therapy, has the same benefits as vocal therapy administered alone.

Self-assessment questionnaires, including quality-of-life questionnaires, are indispensable in clinical practice and

scientific research, as they are assessment tools that aim to analyze treatment outcomes. Regarding the V-RQOL protocol, participants in both groups did not show a statistically significant improvement in voice quality of life after treatment (Table 2). There was an increase in all V-RQOL domain scores. However, the EG maintained this in the results obtained one month after treatment, which was not observed in the CG. There is also a high standard deviation in both groups, which means that the participants' responses varied widely, making it difficult to observe any differences within the small sample size.

Another way to understand the results regarding voice quality of life after treatment in both groups is that because this was a clinical study, vocal therapy was rigorously standardized for all participants, not allowing many variations. Thus, because individual vocal deficiencies based on voice complaints were not addressed, some participants could not perceive an improvement in their voice-related quality of life. Another important factor to consider is that many participants acquired greater vocal self-knowledge in the therapy process. They became more careful in reporting aspects of their voices and their vocal limitations, which may have contributed to worsened V-RQOL responses. Among studies that have used electrical stimulation, only one investigated the impact of voice on patients' quality of life after treatment. LaGorio, Carnaby-Mann, Crary¹⁷ treated elderly people with vocal fold arching using vocal therapy associated with NMES electrical stimulation for three weeks. The authors applied the vocal handicap index (VHI) protocol before and after treatment and found a decrease in the protocol score that was not significant.

Regarding vocal quality self-assessment by category analysis (Table 3), 38.50% of the EG presented vocal self-assessment as "reasonable." Immediately after treatment, 53.80% of the participants considered their voices "good," and 61.60% still rated their voices as "good" one month after treatment, with a tendency to significant difference. The CG also self-rated their voices as "reasonable" (50%) or "bad" (21.4%) in the pre-treatment phase, whereas immediately after, 50% considered their voices to be "good" or "very good" (14.3%). However, this result was different one month after treatment. At that time, 71.4% showed a significant worsening in vocal self-assessment, considering their voices "reasonable." Thus, vocal therapy with TENS followed by vocal exercises was able to maintain positive results regarding vocal self-perception one month after treatment, a fact that did not occur with the CG.

Although participants in both groups noticed an improvement in their voice quality, vocal acoustic analysis did not undergo statistically significant changes. The findings of the present study show that low-frequency TENS vocal therapy followed by vocal exercises seems to be better than vocal exercise therapy alone with regard to self-perception of voice quality and, mainly, in maintaining the quality of life in voice after vocal treatment.

In the present study, the proposed vocal therapy was not able to significantly modify vocal or life quality, which may

have been due to study limitations regarding the number of sessions, consideration of individual needs, adherence to therapy, and/or treatment of comorbidities. It is suggested that more studies be performed with a larger number of therapeutic sessions and for longer periods of time than the one proposed in this study, since the literature reports better results regarding vocal quality for longer vocal treatment times.^{34,38–40,47,52} This may be due to the fact that patients with behavioral dysphonia need more time to modify their habits and behaviors regarding their voices. Perhaps studies that verify the effectiveness of vocal treatment based on patient adherence at the motivational stage may help to better understand the profile of patients seeking a therapeutic process in the voice area.

It is also important to emphasize the need for more long-term evaluations to verify possible behavioral changes that may reflect changes in vocal, laryngeal and life quality. In addition, the importance of continuing the daily practice of vocal exercises at home is reinforced as a way of maintaining the benefits acquired during treatment. As previously mentioned, adaptations may occur over time and the results obtained may be prolonged with continuous training.⁴² Regarding the use of TENS electrical stimulation in vocal treatment, this seems to be a good resource for longer maintenance of therapeutic results.

CONCLUSION

Vocal therapy using low-frequency TENS followed by vocal exercise produced results similar to the vocal therapy without TENS used in the treatment of dysphonic women regarding voice quality, self-perception and quality of life in voice. However, low-frequency transcutaneous electrical nerve stimulation (TENS) therapy followed by vocal exercise was effective in reducing vocal fold lesion size in dysphonic women.

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SUPPLEMENTARY DATA

Supplementary data related to this article can be found online at [doi:10.1016/j.jvoice.2022.08.006](https://doi.org/10.1016/j.jvoice.2022.08.006).

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