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The Role of Oral Steroids in the Treatment of Phonotraumatic Vocal Fold Lesions in Women

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Abstract

1. To determine the short-term effectiveness of oral steroids in women with benign vocal fold lesions.
2. To determine the effectiveness of adjuvant oral steroids in women undergoing voice therapy for benign vocal fold lesions.

Study Design: Randomized, double-blind, placebo-controlled clinical trial

Setting: Tertiary voice care center

Subjects and Methods: Thirty-six patients undergoing voice therapy for the treatment of phonotraumatic vocal fold lesions randomly received either a 4-day course of oral steroids or a placebo prior to initiating voice therapy. Voice Handicap Index-10 (VHI-10) scores, video and audio perceptual analyses, acoustic and aerodynamic analyses at baseline, and patient perception of improvement after a short course of steroids or a placebo and at the conclusion of voice therapy were collected.

Results: Thirty patients completed the study, of which 27 (only female) were analyzed. The primary outcome measure, VHI-10, did not improve after the 4-day course of steroid or placebo. Secondary measures similarly showed no improvement with steroids relative to placebo. Voice therapy demonstrated a positive effect on both VHI-10 and patient-perceived improvement of voice in all subjects.

Conclusion: A short course of oral steroids did not benefit women with phonotraumatic vocal fold lesions. In addition, steroids had little beneficial effect when used adjunctively with voice therapy in this patient cohort.

Keywords

voice; larynx; steroid; glucocorticoids; vocal fold; voice therapy

Introduction

One of the more confounding statements in the recent Clinical Practice Guidelines (CPG) for hoarseness was related to the paucity of evidence for the use of steroids for treating patients with hoarseness.¹ Specifically, the document only suggested a role for steroids to treat ‘allergic laryngitis’ in vocal performers. We previously confirmed that otolaryngologists commonly employ oral steroids for a variety of diagnoses underlying voice complaints.² Despite the widespread use of oral steroids for the treatment of patients with voice complaints, little evidence supports their use.

The mainstays of treatment of benign vocal fold lesions remain behavioral management (voice therapy) and surgical excision. Voice therapy is helpful in the long-term, but its effect is delayed and not helpful, for example, in a performer with an acute issue.^{3–7} Surgical excision similarly requires a commitment to a longer-term process and is not typically used for a short-term fix. Therefore, steroids have traditionally been used in situations where short-term improvement is needed.

A short-term, high dose of oral steroids, such as 30 mg or greater of prednisone equivalent per day, may help reduce the inflammatory component of benign vocal fold lesions and reduce swelling in the striking zone on the vocal fold contralateral to a unilateral lesion. In theory, this reduced swelling would improve glottal configuration and vocal fold vibration, thereby improving overall vocal quality and reducing phonation effort. After taking a short course of steroids, patients may experience not only these immediate effects, but may also then be primed to be better able to initiate the exercises and techniques they learn in voice therapy.

We sought to test this theory by examining the effects of oral steroids on short-term and long-term voice outcomes in patients with benign, phonotraumatic, vocal fold pathology. Specifically, two hypotheses were tested: 1) A short course of oral steroids will reduce self-perceived voice handicap and improve vocal function, and 2) A short course of oral steroids will “prime” patients for improved voice therapy outcomes. These hypotheses were based on our emerging clinical experience as the literature is void of supporting studies.

Materials and Methods

The current study was approved by the Institutional Review Board at the New York University School of Medicine. The general experimental design is summarized in Figure 1. Subjects were recruited from the treatment-seeking population at the Voice Center at NYU Langone Health. Males and females between 18 and 80 with phonotraumatic lesions deemed

causative of dysphonia were included if voice therapy was determined as the initial treatment modality. Exclusion criteria included recent use of any glucocorticoids (oral, inhaled, or intravenous) in the prior three months, presence of significant neurological impairment, history of prior voice therapy, radiation to the neck, laryngeal surgery within the past 12 months, or the presence of any medical condition whereby oral glucocorticoids were contraindicated.

A placebo-controlled, double-blinded, randomized prospective study design was employed. The speech-language pathologist who provided voice therapy and individuals involved in collection and analysis of data were blinded to drug or placebo conditions. Following consent, subjects were randomized to receive a 4-day course of either oral steroids (40mg prednisone daily) or placebo prior to the initiation of voice therapy. Compliance and side effects were assessed through a questionnaire.

Prior to the initiation of therapy but after taking the “drug”, subjects returned for an interim evaluation to collect the videostroboscopic and vocal function measures identical to those collected at baseline (see following section for detailed description of measures). Subjects then initiated voice therapy, receiving 6 weekly sessions. The first session was divided into a brief review of patient symptoms, documentation of therapeutic goals, a discussion of vocal hygiene relevant to the patient, and an introduction of basic training exercises. Subsequent sessions were individualized to specific patient goals, compensatory behaviors, and response to techniques. All sessions included stretches and laryngeal massage techniques to reduce musculoskeletal strain, basic training exercises to optimize coordination of airflow, vocal fold vibration, and resonance (e.g., humming, lip trills, nasal pinch vocalizations, etc.), and carryover work with focused attention to application of basic training techniques. Increased proprioception of vocal strain and resonance was instilled at every level of treatment. Home exercises were audio or video recorded and a written version of the homework provided for improved compliance. Subjects returned after the completion of therapy to obtain videostroboscopic and vocal function measures.

Dependent Variables and Data Collection

Voice Handicap Index (VHI)-10.—Subjects completed the VHI-10 at each visit.⁸ The comparison of VHI-10 scores within subjects from baseline to the subsequent interim and final evaluations served as the primary dependent variable.

Perceptual Analysis.—Laryngeal videostroboscopic imaging (Pentax Medical, Inc., Montvale, NJ) was performed at each visit (baseline, interim, and final). Video clips were prepared to include clear imaging of the pathology for at least 3 seconds of continuous voicing at modal pitch. Three fellowship-trained laryngologists reviewed paired clips (e.g., baseline followed by interim and baseline followed by final) side-by-side in random order. Reviewers rated the second clip in the pair as worse, same, or better than the first clip on four parameters: 1) mucosal wave, 2) glottal closure 3), lesion size, and 4) overall appearance.⁹

In addition, the Consensus Auditory-Perceptual Evaluation of Voice (CAPE-V) stimulus sentences were captured via the Computerized Speech Laboratory (Pentax, Montvale, NJ).¹⁰

Three speech-language pathologists with expertise in voice who were uninvolved in the current experiment rated the overall severity of dysphonia of randomly-presented audio clips using a 100-point visual scale.

Twenty percent of both auditory and video samples were repeated to quantify intra-rater reliability. For each video-perceptual rating, intra-rater reliability and inter-rater agreement were evaluated using Kendall's Coefficient of Concordance (Kendall's W) for ordinal responses. Kendall's W ranges from 0 (no agreement) to 1 (perfect agreement). For auditory-perceptual analyses, intra-rater reliability and inter-rater agreement were evaluated via intraclass correlation coefficient (ICC) estimates.¹¹

Aerodynamic Analysis.—Aerodynamic analyses employed the voicing efficiency protocol of the Phonatory Aerodynamic System (Pentax, Montvale, NJ). While tightly holding the flow mask over their mouth and nose, subjects produced /pa/ five times at their most comfortable pitch and loudness at a rate of approximately 1.5 syllables per second.¹² Pressure and flow signals were monitored in real time to check for pressure tube blockage or improper mask placement. Laryngeal airway resistance (R_{law} in cmH₂O/L/sec) was calculated from the mean peak air pressure (cmH₂O) and mean airflow during voicing (L/sec) from the middle three syllables.

Acoustic Analysis.—In addition to the CAPE-V sentences, subjects produced a sustained /a/ vowel. A frequency-stable, 1.5-second, medial portion of the vowel and the all-voiced sentence “We were away a year ago” were used to calculate the Acoustic Voice Quality Index (AVQI) v. 3.01 via an automated Praat script.^{13,14} The AVQI combines six acoustic measures in a linear model to arrive at a single multivariate measurement that correlates with auditory-perceptual judgement of voice quality.

Patient-Reported Measures.—At the interim visit, subjects described the effect of the “drug” on overall change in voice and on vocal quality relative to baseline as “better, worse, or same”. Subjects also reported compliance with medication and any adverse events or side effects. Following completion of voice therapy, subjects again rated change (better, worse, or same) in overall voice and vocal quality. The responses of “worse” and “same” were collapsed into a single group for binary analysis (improvement/no improvement).

Statistical Analysis

Based on a review of our clinical outcomes, we assumed a VHI-10 of 10 (SD=7) for the placebo plus voice therapy group and a VHI-10 of 14 (SD=7) for the steroid plus voice therapy cohort. Using these assumptions with an alpha error level of 0.05 and a power of 80%, a sample size of 20 in each group was determined to be adequate to demonstrate a statistical difference between the groups.

Repeated measures ANOVA was used to analyze the effects of drug type (steroid or placebo), time point, (baseline, interim, or final visit) and interaction between drug type and time point on the continuous outcome variables (VHI-10, auditory-perceptual ratings, and the acoustic and aerodynamic measures). In the case of a significant main effect or interaction, post-hoc pairwise t-tests were used to compare group differences. One-tailed t-

tests were selected to match our directional hypotheses. Cohen's *d* effect sizes were also calculated to explore the magnitude of any significant differences.

The video-perceptual ratings of worse, same, and better were coded as -1, 0, and 1, respectively. The non-parametric Wilcoxon Rank Sum Test was used to test for differences between steroid and placebo groups in the mean ratings of each of the four video-perceptual parameters. Additionally, the Wilcoxon Rank Sum Test was used to test the hypothesis that each parameter would be judged as improved (mean rating > 0) at each time point.

The chi-squared test for equality of proportions was used to test for differences between steroid and placebo groups on the binary outcome variables of patient-reported improvements in overall voice and voice quality, as well as the occurrence of reported side effects at the interim and final visits. All statistical analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC) or R version 3.4.3 running in RStudio.^{15,16}

Results

Thirty subjects completed the study (27 females and 3 males). Due to the low number of male subjects, only data from female subjects were analyzed. The average age of the final study cohort was 27.4 years (7.07 SD). Fourteen of the 27 subjects received steroids and 13 received a placebo. Twenty-two of the subjects were diagnosed with bilateral lesions. Twenty-four of the subjects had lesions with an inflammatory component, defined as edema and erythema surrounding the lesion(s).

Voice Handicap Index (VHI)-10.

Repeated-measures ANOVA confirmed a main effect of time point on VHI-10 score ($F_{2,50} = 3.411$, $p = 0.04$, Figure 2). No main effect for drug type was observed ($F_{2,25} = 0.31$, $p = 0.58$). Similarly, no interaction between time point and drug type ($F_{2,50} = 0.055$, $p = 0.95$) was noted. Post-hoc pairwise one-tailed *t*-tests between VHI-10 scores at the three time points revealed lower (improved) VHI-10 scores across all subjects (steroid and placebo groups combined) at the final visit compared to both the baseline and interim visits ($p = 0.04$ and $p = 0.02$, respectively). However, Cohen's *d* indicated small effect sizes in these differences with 95% confidence intervals crossing zero for both the baseline compared to final visit ($d = 0.35$ [-0.20, 0.90]) and the interim compared to final visit ($d = .40$ [-0.15, 0.95]). No difference in VHI-10 was observed between baseline and interim visits ($p = 0.72$).

Perceptual Ratings.

Table 1 shows interrater and intrarater reliability of video-perceptual ratings. Due to moderate agreement between the three raters, the median rating for each of the four visual-perceptual parameters was employed to test differences in ratings between the steroid and placebo groups and the effect of time point (improvement at interim visit and improvement at final visit). No significant differences were noted in the distribution of ratings between the steroid and placebo groups in any of the four video-perceptual ratings ($p > 0.05$). Therefore, the steroid and placebo groups were combined to test for improvements at the interim and final visits. At the interim visit, raters judged all ratings (mucosal wave, glottal closure,

lesion size, and overall appearance) as improved (mean rating > 0) relative to baseline (Figure 3). At the final visit, raters only judged two ratings, mucosal wave and overall appearance, as improved relative to baseline. Overall, raters judged the average videostroboscopic appearance of all subjects as improved at both the interim and final visits relative to baseline.

Auditory-perceptual ratings had poor interrater reliability (ICC = 0.427, 95% CI: 0.209 to 0.603). Intrarater reliability was poor for two raters (ICC = 0.267, 95% CI: -0.204 to 0.642; ICC = 0.32, 95% CI: -0.149 to 0.675) and good for the third rater (ICC = 0.706, 95% CI: 0.378 to 0.878). Given the poor reliability, further group analysis was not performed.

Laryngeal Airway Resistance.

Two subjects in the steroid group did not reliably complete the aerodynamic testing at the interim visit and were removed from analysis. Repeated-measures ANOVA revealed a main effect of time point on R_{law} ($F_{2,46} = 6.984$, $p = 0.002$), but no main effect of drug type ($F_{1,23} = 1.058$, $p = 0.31$) and no interaction between time point and drug type ($F_{2,46} = 1.955$, $p = 0.15$). Post-hoc pairwise one-tailed t-tests comparing R_{law} at the three time points revealed lower (improved) R_{law} across all subjects (steroid and placebo groups combined) at the interim and final visits compared to baseline ($p = 0.001$ and $p = 0.006$, respectively), with medium effect sizes from both the baseline to interim visit ($d = 0.68$, 95% CI: 0.10 to 1.27) and baseline to final visit ($d = 0.54$, 95% CI: -0.04 to 1.12). No significant difference in R_{law} was observed between interim and final visits ($p = 0.21$). Therefore, R_{law} decreased at the interim visit in both drug groups and that decrease was maintained after voice therapy.

AVQI.

Similar changes were observed in the composite acoustic measure, AVQI. A significant main effect for time on AVQI ($F_{2,50} = 4.473$, $p = 0.02$) was observed with no effect of drug type ($F_{1,25} = 0.059$, $p = 0.81$) and no interaction between time and drug ($F_{1,50} = 0.92$, $p = 0.41$). A decrease in AVQI from the baseline visit compared to both the interim and final visits ($p = 0.01$ and $p = 0.007$, respectively) drove this main effect of time. The difference in AVQI between the interim and final visits did not achieve significance ($p = 0.22$). Cohen's d indicated medium effect sizes with confidence intervals just crossing zero for both the baseline visit versus the interim visit ($d = 0.46$ [-0.09, 1.01]) and the baseline versus the final visit ($d = .51$ [-0.04, 1.07]).

Patient-reported measures.

At the interim visit the majority of subjects in both groups reported no improvement in overall vocal ability or vocal quality (Table 2). Furthermore, no differences were observed in the proportion of subjects who reported overall improvement in vocal ability between the steroid and placebo groups ($X^2 = 0.60$, $p = 0.48$). Similarly, the proportion of subjects who reported improved vocal quality between the steroid and placebo groups was not significant ($X^2 < 0.001$, $p = 1$).

Self-reported data were missing from three subjects at the final visit following voice therapy (Table 2). All but one subject reported overall improved vocal ability and voice quality, indicating voice therapy was helpful regardless of drug group. Only one subject in the

placebo group reported her overall vocal ability and quality were the same after voice therapy.

The same proportion of subjects reported side effects in both the steroid and placebo groups. Eight out of the 15 subjects who received steroids reported minimal side effects, and 5 out of 12 subjects in the placebo group also reported minimal side effects ($\chi^2=0.008$, $p=0.93$). In the subjects who took steroids, 7/15 reported trouble sleeping, two subjects reported euphoria, and one each reported bloating and increased appetite. Subjects on placebo reported increased appetite (3/12), and one each reported trouble sleeping, euphoria, anxiety, bloating, and sinus infection/URI.

Discussion

The discovery of glucocorticoids in the 1940's to treat severe rheumatoid arthritis irreversibly changed the treatment of inflammatory disorders and led to the award of a Nobel Prize.¹⁷ Steroids have since found their way into everyday clinical use for a variety of disorders. Otolaryngologists use steroids in the treatment of facial nerve disorders, chronic sinusitis, and airway disorders, among others.^{18–25} Although used commonly for the treatment of voice disorders, very little evidence exists to support or direct their use. We sought to determine the efficacy of this category of drugs in the treatment of a variety of commonly diagnosed benign vocal fold lesions.² This study was unique in that it represents a placebo-controlled double blinded prospective trial. This type of study was necessary to ascertain the true effects of steroids, given that these drugs likely carry a strong clinical bias and placebo effect.

This study did not demonstrate a measurable effect of the short course of oral steroids on self-perceived vocal handicap, vocal function, or laryngeal appearance in women with benign vocal fold lesions, which is contrary to both our hypothesis and clinical experience. However, the data are fairly consistent across multiple outcome measures. In contrast, subjects did experience significant improvements with voice therapy, regardless to which experimental group they were randomized. Many factors could explain the lack of response in this patient cohort. Treatment course was fairly short and was standardized to a single dose, regardless of weight to aid in blinding and to improve compliance. However, this treatment course may not have been ideal to obtain a relevant clinical effect. Although nearly all (24/27) of the patients were diagnosed with lesions with an inflammatory component, it is possible this inflammation made only a small contribution to each subject's dysphonia. Therefore, even if the steroid treatment reduced vocal fold inflammation, the persistent lesion would have continued to impede vocal fold function.

Sample size was likely problematic. We did not reach our target recruitment of 20 subjects per group, as determined by our power analysis, and a larger sample size would have allowed for improved comparison between groups and experimental insight. However, very few of the comparative outcome measures even neared significance. As such, the lack of improvement with this particular course of steroid is likely real.

Of course, this study may have been limited by the lack of good outcome measures. Despite our best effort to be comprehensive in including multiple types of outcome measures, most of these measures were problematic. Audioperceptual ratings were unreliable and had to be discarded. Even videoperceptual ratings had only moderate agreement. VHI-10 ratings are subjective and, therefore, can be governed by a placebo effect. Acoustic measures likely have less fidelity in cases with only mild to moderate pathology, as was the case in most of our subjects. Both in this study and in our clinical experience, patients report feeling better after taking a short course of steroids. Either we have not yet found an appropriate outcome measure to capture the patient-perceived improvement, or it is simply a placebo effect. To mitigate these issues, future similar studies would likely benefit from studying more severely dysphonic patients.

Conclusions

This double-blinded, placebo controlled trial of a short course of oral steroids prior to the initiation of voice therapy did not demonstrate improvement in women with benign vocal fold lesions.

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CONSORT 2010 Flow Diagram and Experimental Overview

Figure 1.
CONSORT 2010 flow diagram and general experimental paradigm for the study.

Figure 2.

Plots showing the main effect of time point on Voice Handicap Index-10 (VHI), laryngeal airway resistance (Rlaw), and Acoustic Voice Quality Index (AVQI).

Figure 3.
Distribution of video-perceptual ratings (drug groups combined, * $p < 0.05$).

Table 1.

Interrater reliability and intrarater reliability (Kendall's W) for the four video perceptual ratings of stroboscopic exams.

Videostroboscopic Rating	Interrater reliability	Intrarater reliability		
		<i>Rater A</i>	<i>Rater B</i>	<i>Rater C</i>
Mucosal Wave	0.48	0.65	0.95	0.50
Glottal Closure	0.52	0.89	0.89	0.83
Lesion Size	0.55	0.87	0.95	0.58
Overall Appearance	0.57	0.78	0.95	0.57

Table 2.

Patient-reported ratings of improvement in overall voice and in vocal quality at the interim (post-steroid or post-placebo) and final (post-therapy) visits relative to baseline.

Time	Group	Voice improved overall		Vocal quality improved	
		Yes	No	Yes	No
Interim Visit (n=27)	Steroid	2	13	4	11
	Placebo	4	8	4	8
Final Visit (n=24)	Steroid	13	0	13	0
	Placebo	10	1	10	1