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Randomized Controlled Trial of Supplemental Augmentative and Alternative Communication versus Voice Rest Alone after Phonomicrosurgery

Bernard Rousseau, Ph.D., Michelle L. Gutmann, Ph.D., I-fan Theodore Mau, M.D., Ph.D., David O. Francis, M.D., MPH, Jeffrey P. Johnson, MS, Carolyn K. Novaleski, M.S., Kimberly N. Vinson, M.D., and C. Gaelyn Garrett, M.D.

Bernard Rousseau, Departments of Otolaryngology, Hearing and Speech Sciences, and Mechanical Engineering, Vanderbilt University School of Medicine; Michelle L. Gutmann, Department of Hearing and Speech Sciences, Vanderbilt University School of Medicine; Ted Mau, Department of Otolaryngology-Head and Neck Surgery, University of Texas Southwestern Medical Center; David O. Francis, Department of Otolaryngology, Vanderbilt University School of Medicine; Jeffrey P. Johnson, Department of Speech, Language, and Hearing Sciences, Boston University; Carolyn K. Novaleski, Department of Hearing and Speech Sciences, Vanderbilt University School of Medicine; Kimberly N. Vinson, Department of Otolaryngology, Vanderbilt University School of Medicine; Gaelyn Garrett, Department of Otolaryngology, Vanderbilt University School of Medicine

Abstract

Objective—This randomized trial investigated voice rest and supplemental text-to-speech communication versus voice rest alone on visual analog scale measures of communication effectiveness and magnitude of voice use.

Study Design—Randomized clinical trial.

Setting—Multicenter outpatient voice clinics.

Subjects—Thirty-seven patients undergoing phonomicrosurgery.

Methods—Patients undergoing phonomicrosurgery were randomized to voice rest and supplemental text-to-speech communication or voice rest alone. The primary outcome measure was the impact of voice rest on ability to communicate effectively over a seven-day period. Pre- and post-operative magnitude of voice use was also measured as an observational outcome.

Results—Patients randomized to voice rest and supplemental text-to-speech communication reported higher median communication effectiveness on each post-operative day compared to those randomized to voice rest alone, with significantly higher median communication effectiveness on post-operative day 3 ($p = 0.03$) and 5 ($p = 0.01$). Magnitude of voice use did not differ on any pre-operative ($p > 0.05$) or post-operative day ($p > 0.05$), nor did patients significantly decrease voice use as the surgery date approached ($p > 0.05$). However, there was a

significant reduction in median voice use pre- to post-operatively across patients ($p < 0.001$) with median voice use ranging from 0–3 throughout the post-operative week.

Conclusion—Supplemental text-to-speech communication increased patient perceived communication effectiveness on post-operative days 3 and 5 over voice rest alone. With the prevalence of smartphones and the widespread use of text messaging, supplemental text-to-speech communication may provide an accessible and cost-effective communication option for patients on vocal restrictions.

Keywords

randomized controlled trial; voice; voice disorders; voice rest; text-to-speech; augmentative and alternative communication

Introduction

Pre-operative voice therapy by a trained speech language pathologist, post-operative voice conservation techniques, and vocal abuse during the post-operative period are the strongest predictors of surgical outcome in microlaryngeal surgery (Koufman & Blalock, 1989). The latter, vocal abuse during the post-operative period is the most strongly correlated predictor of prolonged post-operative dysphonia (Koufman & Blalock, 1989). This has led to the common practice of tissue immobilization (i.e., voice rest) during the immediate post-operative period to minimize post-operative dysphonia risk¹.

Patients prescribed voice rest often find it challenging to adhere because of a lack of practical communication alternatives². This is particularly true for patients in vocally demanding occupations where voice rest leads to work-related absenteeism and has a significant impact on communication-related employment functions².

Until the last 10 years, augmentative and alternative communication aids have been used primarily by populations temporarily or permanently unable to speak³. However, when considered more broadly, augmentative and alternative communication has expanded significantly and is now a staple means of communication in western culture (e.g., texting using a smartphone).

Interestingly, in a previous investigation on voice rest compliance, though we were primarily interested in patient adherence to treatment, incidentally we found that a large majority of patients employed some form of augmentative and alternative communication to adhere to voice rest². That is, augmentative and alternative communication is a common approach employed by patients prescribed voice rest. We found that in order to be adherent to treatment, the patients in that study reported adopting a variety of methods of alternative communication to effectively manage voice rest, with nearly 80% of adherent patients reporting the use of texting or email to communicate while on voice rest². These findings provided motivation for the current randomized controlled clinical trial aimed at investigating the effects of voice rest and supplemental text-to-speech communication versus voice rest alone on communication effectiveness during voice rest.

The primary outcome measure was the impact of voice rest on the ability to communicate effectively without using the voice or whispering over a seven day period of treatment. Patients were randomized to receive: 1) voice rest and supplemental text-to-speech (TTS) communication or 2) voice rest alone. We were also interested in patients' perceived magnitude of voice use during the days leading up to surgery and for the period of time of voice rest following surgery. These secondary measures were also determined and treated as observational variables for purposes of this randomized controlled clinical trial.

Methods

Participants

This randomized controlled clinical trial was performed in accordance with the Declaration of Helsinki, Good Clinical Practice, approved by the Vanderbilt Institutional Review Board (#110673) and University of Texas Southwestern Medical Center Institutional Review Board (#022012-061). Research participants were 37 patients (24 males, 13 females) between 23–71 years of age ($M = 43.81$, $SD = 13.58$). Participants were recruited from two tertiary care laryngology practices (Vanderbilt University Voice Center and University of Texas Southwestern Clinical Center for Voice Care). Inclusion criteria required prospective patients to be 18 years of age or older, be scheduled for phonosurgery to remove a vocal fold lesion, and be prescribed post-operative voice rest for up to seven days (M days = 6.70, $SD = 0.62$, range = 4–7).

Procedures and Text-To-Speech Communication Device

Participants were randomized to voice rest and supplemental TTS communication ($N = 18$) or voice rest alone as control ($N = 19$). Participants in both the experimental and control groups met with key study personnel once pre-operatively to receive instructions from their surgeons to observe strict voice rest (i.e., no talking at any volume for any duration including whispering), to provide research consent, and to receive instructions specific to their study group assignment. Participants who were randomized to receive supplemental TTS communication also received a 20-minute standardized orientation session at this time to introduce them to the Lightwriter® speech generating device. Randomization was implemented in blocks of three to ensure balance across both treatment groups. All physicians were blinded to group assignment to mitigate allocation bias. The Lightwriter® SL-40 is a portable, dedicated speech generating device with a two-sided display and interchangeable keyboard (QWERTY or ABCD layout) that allows literate users to communicate via typing words, phrases, or sentences which are then spoken out loud. The Lightwriter SL-40 supports rate enhancement features such as word prediction and an attention-getting bell. Those randomized to the experimental group were asked to complete TTS device competency training to ensure that they demonstrated a minimum level of proficiency. Participants in the control group were not provided with any specific instructions on alternative communicative devices or strategies. Please refer to the CONSORT diagram provided in Figure 1.

Outcomes

The primary outcome measure was the effect of voice rest on the participant's ability to communicate effectively, which was assessed using a 10-cm visual analog scale (VAS) in response to the statement: "*I was able to communicate effectively today without using my voice or whispering.*" The VAS was anchored at 0 (*not at all*) and 10 (*very much*). Responses were entered daily for up to seven days post-operatively. Magnitude of voice use was treated as a secondary outcome variable and measured using a 10-cm VAS in response to the question: "*How much did you use your voice today (including whispering)?*" The VAS was anchored at 0 (*not at all*) and 10 (*every time I wanted to communicate*). Responses were entered daily for seven days pre-operatively and up to seven days post-operatively. Pre- and post-surgical data were collected and entered into a secure Research Electronic Data Capture database⁴.

Statistical Analysis

Participant social and demographic information included age, gender, education (high school, some college, college, advanced degree), number of adults and children in household, and Voice Handicap Index⁵. In addition, lesion type was recorded (e.g., polyp, cyst). Univariate analyses were computed using Wilcoxon-Rank Sum and chi-square tests, as appropriate. *A priori* power calculations were used to determine power and sample size requirements providing an estimate of 17 participants per group to yield 0.8 power to detect 1 SD between group difference at $\alpha = 0.05$. All analyses were performed using STATA MP 12.1⁶.

Results

Participant Demographics

There were no differences in baseline patient characteristics, degree of vocal handicap (total median VHI = 47 and 46 for TTS and control, respectively, $z = 0.67$, $p = 0.51$), or indications for surgery (Table 1). The most common indication for surgery was polyp or cyst, with 88.2% in the TTS and 62.5% in the control group, respectively ($\chi^2 = 3.32$, $p = 0.07$; Table 1).

Communication Effectiveness

Participants randomized to voice rest and supplemental text-to-speech communication reported higher median VAS communication effectiveness on each post-operative day compared to those randomized to voice rest alone, with significantly higher median VAS communication effectiveness on post-operative day 3 (median VAS 58.5 versus 47.5, $z = -2.14$, $p = 0.03$) and 5 (median VAS 70 versus 32; $z = -2.60$, $p = 0.01$; Figure 2). Median VAS communication effectiveness values are provided in Table 2.

Magnitude of Voice Use

Median magnitude of voice use did not differ on any day during the pre-operative ($p = 0.86$, Figure 3) or post-operative week ($p = 0.34$, Figure 3), nor did patients significantly decrease magnitude of voice use as the surgery date approached ($p = 0.34$, Figure 3). However, there

was a significant reduction in median VAS magnitude of voice use pre- to post-operatively (median VAS 69 versus 0, $z = 6.661$, $p < 0.001$, Figure 4) for both groups, with median VAS magnitude of voice use ranging from 0–3 throughout the post-operative week.

Discussion

Despite the widespread use of AAC interventions for children with autism⁷, developmental disabilities^{8,9}, and amyotrophic lateral sclerosis^{10,11} (Ball, Beukelman, & Pattee, 2004; Ball, Willis, Beukelman, & Pattee, 2005), there remains little evidence regarding its use with communication disorders in other contexts such as voice disorders. In the present study, participants randomized to voice rest and supplemental text-to-speech communication reported higher median VAS communication effectiveness on each post-operative day and significantly higher median VAS communication effectiveness on post-operative days 3 and 5 compared to those randomized to voice rest alone. One possible explanation for these findings is that communication partners engaged patients using supplemental TTS communication more, knowing that they had a way to respond. This is an interesting hypothesis and one that is supported by Fried-Oken et al.¹², who found that communication partners tended to request more information from augmentative and alternative communication users when they used a speech-generating device and perceived the speaker to be more cognitively and linguistically competent than when using a dry-erase board. Anecdotally, a common experience of patients using dry erase boards or other manual written methods of alternative communication while on voice rest is a feeling of handicap². Fried-Oken et al.¹² also observed that when a patient in the intensive care unit used a Lightwriter® TTS communication device, medical personnel spent more time listening and their conversational exchanges involved more than just yes/no questions. Thus, another explanation for the findings of the present study of higher median VAS communication effectiveness in participants randomized to voice rest and supplemental text-to-speech communication versus voice rest alone may be the increase in opportunities for more natural conversational exchange between TTS users and their communication partners.

In western societies, technology has emerged as a common method of augmentative and alternative communication, as witnessed by the increased popularity of text messaging via smartphones and tablets. The application of augmentative and alternative communication in this context represents a new application in the treatment of voice disorders. The way in which an augmentative and alternative communication user interfaces with their speech generating device, the type of input (e.g., keyboard or touch screen), and the quality of speech output are all important considerations in the selection of an augmentative and alternative communication system. Some other important considerations include the portability of the system, convenience, and ease of use. The advantages provided by text-to-speech communication over other forms of alternative communication is that TTS communication supports conversational exchange across time and space and does not necessarily require visual contact (e.g., the user is not limited to face to face interactions), allowing this form of communication to be used in a wider range of contexts, including over the telephone. With the prevalence of smartphones and other portable digital media players, the widespread availability of short message service, multimedia messaging service, and text-to-speech ‘apps’ for mobile devices, the application of augmentative and alternative

communication in this setting would appear to be economical and readily accessible for many patients.

A secondary outcome of this randomized controlled trial was to determine the magnitude of voice use for the period immediately prior to and immediately after phonosurgery. For this observational outcome, we were interested in not only the magnitude of voice use following the period of surgery, but also whether patient perceived magnitude of voice use was influenced by the impending surgery itself. That is, we were interested in determining whether patients habitually modify their vocal behaviors (e.g., increase or decrease median VAS magnitude of voice use), knowing that they will soon be expected to adhere to a period of strict vocal rest. For this observational outcome, we measured perceived magnitude of voice use daily for seven days pre-operatively and up to seven days post-operatively. Examination of the magnitude of voice use data revealed important results. Median VAS magnitude of voice use did not differ on any day during the pre-operative or post-operative week, nor did patients significantly decrease magnitude of voice use as the surgery date approached. However, there was a significant reduction in median VAS magnitude of voice use pre- to post-operatively for both groups, with median VAS magnitude of voice use ranging from 0–3 throughout the post-operative week. In other words, notwithstanding group assignment, patients in both groups managed to decrease the overall magnitude of voice use pre- to post-operatively during the voice rest period. These observations are noteworthy as they may provide us with additional insight into understanding patient perceptions regarding voice use before and after surgery. First, these data revealed that patients did not appear to be influenced by the impending surgery, as they did not modify their overall magnitude of voice use as the surgery date approached. Second, in a previous study on adherence to voice rest treatment, when using a more strict criteria for voice rest adherence we observed that nearly two-thirds of patients were not compliant with voice rest recommendations². In that study, voice rest compliance was measured dichotomously, in the same way that adherence is often determined clinically. Generally, when a post-surgical patient returns to the clinic following a period of voice rest, the provider determines adherence to voice rest by asking patients whether they used their voice while on voice rest. For example, “I did not use my voice while on voice rest” or “I used my voice while on voice rest”. In contrast, in this randomized controlled clinical trial we were interested in the perceived magnitude of voice use (whether or not patients were adherent to voice rest recommendations). Thus, rather than placing emphasis on strict adherence, the focus was on capturing voice use on a VAS continuum, to gain a better appreciation for the nuances of voice use (including whether or not a patient whispered) on each post-operative day. The VAS is better able to capture the gradations of daily voice use during the voice rest period and does not penalize patients for non-compliance in the same way that traditional self-report systems that are used clinically do. For example, if a patient utters a single word during the voice rest period, they have no choice but to report “non-compliance” using a dichotomous measurement approach, whereas on a continuous measurement scale, they can provide a more accurate estimate of the actual magnitude of voice use. What is particularly noteworthy about the findings of the present study is that these data revealed that while patients may not be strictly adherent to voice rest recommendations, they do manage to decrease the overall magnitude of voice use pre- to post-operatively. In traditional

dichotomous compliance measurement, these patients would have been labeled as non-compliant with voice rest or 80% compliant (i.e., to indicate partial compliance). In our study, while these patients may have used their voices during the voice rest period, these data reveal that patients used their voices median VAS 0–3 of the times that they needed to communicate. Another important distinction between the present randomized controlled clinical trial and our previous retrospective review of patient adherence to voice rest (for any indication) is that all patients in the present study were undergoing voice rest for surgery. It is likely that post-surgical patients are more invested in their outcomes than patients undergoing voice rest for other reasons (e.g., acute laryngitis, hemorrhage). In fact, previously we found that patients undergoing post-operative voice rest were generally more compliant than patients undergoing voice rest for indications other than post-surgical recovery (median VAS 42.4 versus 16.0, $p=0.04$).

One limitation of the VAS measure is that it does depend on perceived magnitude. Thus, there is always the potential for patients to provide an overestimate or underestimate of the measure than actual because of the desire to appear compliant. Nevertheless, VAS measures are widely used in psychometric research and generally provide a more valid measure of raters' judgments than Likert scaling and similar measurement approaches. With recent advances in ambulatory voice monitoring, it may be possible in the future to supplement patient self-reported levels of adherence with objective voice outcomes using voice dosimetry¹³ or ambulatory phonation monitoring¹⁴.

Conclusion

Supplemental text-to-speech communication increased patient perceived communication effectiveness on post-operative days 3 and 5 over voice rest alone. These data suggest that patient use of text-to-speech communication as a supplement to voice rest may provide an advantage in communication effectiveness over voice rest alone. The application of text-to-speech communication in this context represents a new application of augmentative and alternative communication in the treatment of voice disorders. Text-to-speech communication supports conversational exchange across time and space and does not necessarily require visual contact, allowing this form of augmentative and alternative communication to be used in a wider range of contexts, including over the telephone. With the prevalence of smartphones, portable digital media players, and the widespread use of short message service and multimedia messaging service, the use of augmentative and alternative communication for patients on temporary vocal restrictions following phonosurgery may provide a readily accessible and cost-effective alternative communication option.

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Figure 1.

A CONSORT diagram that illustrates the procedures of randomization, allocation, follow-up, and analysis..

Figure 2. Median VAS communication effectiveness ($\pm$ SD) in participants randomized to control (dark shaded) and TTS (light shaded) groups on post-operative (P) days 1–7. Asterisk denotes statistical significance.

Figure 3.

Median VAS magnitude of voice use ($\pm$ SD) in participants randomized to control (black line) and TTS (gray line) groups on pre-operative days (1–7) and post-operative (P) days 1–7.

Figure 4. Median VAS magnitude of voice use ($\pm$ SD) for all patients on pre-operative days (1–7) and post-operative (P) days 1–7.

Table 1

Participant Demographics

Characteristics		Cases (N=17)	Controls (N=16)	P
Age, years median (IQR)		39.5 (28 – 54)	43 (36 – 55)	0.32
Gender	Male	66.7%	63.2%	0.82
	Female	33.3%	36.8%	
Education	Less or Equal to High School	22.2%	31.6%	0.93
	Some College	11.1%	10.5%	
	College	33.3%	26.3%	
	Advanced Degree	33.3%	31.6%	
Other Adults in Household median (IQR)		1 (1 – 2)	1 (1 – 1)	0.25
Children in Household median (IQR)		0 (0 – 1)	1 (0 – 2)	0.07
Polyp/Cyst		88.9%	63.2%	0.07
VHI, total median (IQR)		47 (24 – 69)	46 (34 – 69)	0.51

Table 2

Median VAS Communication Effectiveness on Each Post-operative Day.

Post-operative day	Voice rest and text-to-speech communication	Voice rest alone	P
1	69.00	30.00	0.16
2	62.00	46.50	0.09
3	58.50	47.50	*0.03
4	58.00	49.50	0.16
5	70.00	32.00	*0.01
6	62.50	48.00	0.11
7	74.09	47.00	0.16

* indicates statistical significance.