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Critical Review:
The impact of the Provox FreeHands heat and moisture exchange (HME)® tracheostoma valve on compliance, quality of life and voice quality in tracheoesophageal (TE) speakers.

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This critical review examines the evidence regarding the impact of the Provox FreeHands HME® on compliance, quality of life and voice quality in tracheoesophageal speakers. All of the studies evaluated in this review were repeated measures designs. Overall, tracheoesophageal speakers prefer using the hands-free device, despite the associated disadvantages and conflicting results on voice quality because it minimizes their disability and allows them to use their hands while conversing. Recommendations for further research and clinical implications are provided.

Introduction

Communication not only involves speech but rather a plethora of non-verbal components, including the use of hands to gesture. One of the remarkable developments following a laryngectomy has been the restoration of voice by means of a prosthetic device (Fukimoto, Madison & Larrigan, 1991). Many laryngectomees using this device have noted that finger occlusion highlights their disability and makes it difficult to communicate with gestures and speak while performing certain tasks (van den Hoogen, Meeuwis, Oudes, Janssen & Manni, 1996). Additionally, Blom, Singer and Hamaker (1982) argued that manual occlusion is "inconvenient, non-hygienic, and draws attention to the laryngectomized condition" (as cited in Fujimoto, Madison & Larrigan, 1991, p. 33). It was with this outlook that the development of hands-free devices came into existence, in the hope of normalizing communication and perhaps improving quality of life (Lorenz, Groll, Ackerstaff, Hilgers & Maier, 2007).

Previous research has ascertained that individuals who use moisture exchange devices, in addition to hands-free valves, might experience ease of breathing and speaking, which could possibly influence quality of life, improve voice quality and reduced frustration with communication (Eadie & Doyle, 2005; van As, Hilgers, Koopmans-van Beinum & Ackerstaff, 1998). Nonetheless, previous hands-free tracheostoma valves have yielded various problems resulting in unsuccessful attempts of users to comply with hands-free speech; most notably, increased pressure while voicing, airflow resistance and seal fixation (van de Hoogen et al., 1996). The Provox FreeHands heat and moisture exchange (HME) ® has been developed to address some of these aforementioned concerns (Hilgers et al., 2003).

The Provox FreeHands HME ® contains a light plastic cassette (containing an elastic membrane) that slides into a base-plate that attaches to the skin. When pressure increases to produce voice, the coiled membrane unravels, occludes the stoma and is held in that position by a magnet until the pressure drops (Hamade, Hewlett & Scanlon, 2006). Thus, the laryngectomee has the ability to gesture while speaking.

Objectives

The primary objective of this paper is to critically evaluate the recent literature on the Provox FreeHands HME® that report on compliance, voice quality and quality of life (QOL). The secondary objective is to provide recommendations for continued research and evidence-based clinical practice.

Methods

Search Strategy

Internet databases, including PubMed, SCOPUS, Scholar's Portal and CINAHL were searched with the following terms:
((hands-free speech) OR (Provox FreeHands HME) OR (automatic tracheostoma valve)) AND ((laryngectomy) OR (quality of life) OR (voice quality) OR (compliance) OR (speech therapy) OR (rehabilitation)).
The search was limited to articles in English. There was no limitation on the date of the articles.

Selection Criteria

Studies selected for inclusion in this critical review were required to investigate the effects of the Provox FreeHands HME® on patient compliance, quality of life and/or voice quality in tracheoesophageal (TE) speakers. No limits were set on the demographics of the participants, outcome measures or previous experience with a hands-free device

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Data Collection

The data search yielded five papers that fit in the abovementioned search criteria. The reviewed studies were all experimental and longitudinal, using non-randomized, crossover repeated measure/within subject designs. Outcome measures were both quantitative (i.e., acoustic analysis) and qualitative (i.e., questionnaire).

Results

The studies below are within subject/repeated measures designs; conditions are always exactly equivalent with respect to individual difference variables since the participants are the same in the different conditions and act as their own control. Crossover designs encompass a carryover effect; thus, the participants in one condition may affect performance in other conditions.

Hilgers et al. (2003) investigated the development and testing of the new Provox FreeHands HME® on patient compliance and voice quality in 20 laryngectomized individuals. The participants were randomly chosen from a population of 180, consisting of 15 men and 5 women (mean age of 62). All participants, except 1, were daily Provox HME® users and 5 were daily automatic stoma valve (ASV) users (Blom-Singer) prior to the study. The study consisted of three successive prototype trials. Only 15 participants remained in the study due to problems unrelated to the valve and therefore, only results from trial two are reported in the study. A structured questionnaire was completed after three weeks once the trial period was over. This questionnaire focused on efficacy of the valve and adhesion to the skin. Voice recordings were used to test for Maximum Phonation Time (MPT) and dynamic loudness. Read aloud text was also used to establish pauses. These data were collected for the three stoma-occlusion methods.

The Paired Student's t-test was used to analyze differences between the three stoma occlusion methods. The results indicated that 11 participants used the Provox FreeHands HME ® on a daily basis, 2 of the users found speaking easier, 3 experienced no difference and 4 considered speaking more difficult. Of the 5 daily ASV users, 3 preferred the Provox FreeHands HME® to the Blom-Singer ATV®. Of the 10 remaining, 6 continued to use the Provox FreeHands HME® after the study on a daily basis and 3 would use it "on occasion". The Provox FreeHands HME® yielded a louder voice. No difference in voice perception of both the Provox HME® and Provox FreeHands HME® was noted. MPT was the longest with the Provox HME®; however, the Provox FreeHands HME® was longer than the Blom- Singer ATV®.

This within subject provided level II experimental evidence, one below the most ideal 'gold standard' of experimental design. One of the limitations of this study was the lack of information provided on validity, reliability or standardization of the questionnaire. Further, this study was funded by the manufacturers and could have therefore attributed to experimenter bias. Order effect could have been a factor since there was no mention of randomization of the devices. Additionally, 5 participants had experience with a hands-free device prior to the study and could have accounted for participant bias. Three of the participants did not test the Blom-Singer ATV®, which could have confounded the results. Because of the abovementioned limitations as well as the small sample size, one must make cautious interpretations of the research provided.

Op de Coul et al. (2005) performed a longitudinal repeated measures study to determine compliance, quality of life and voice quality of the Provox FreeHands HME® in 79 laryngectomized individuals that were recruited from 4 head and neck cancer centers in The Netherlands. The sample size was sufficient to detect a large effect size. Eight participants had previous experience with the Blom-Singer ATV® and 75% were daily HME users. Three questionnaires were given at baseline, after 1 and after 6 months. One questionnaire asked about device function while the other two questionnaires assessed quality of life (European Organization and Research for Treatment of Cancer QOL C30 and Head & Neck 35). Scores were transformed to a scale of 0 to 100. The device questionnaire was scaled according to Likert's method. After 1 and 6 months, data were collected on MPT and dynamic loudness for the three stoma occlusions methods (Provox HME®, Provox FreeHands HME®, Blom-Singer ATV®). Three investigators rated perceived voice quality as 'good', 'reasonable' or 'poor' based on intelligibility, pitch, frequency, etc.

Valid and reliable standardized questionnaires were employed where Cronbach's alpha was used to test internal reliability. Statistical analysis was calculated using Pearson' correlation. Differences over time within groups and voice parameter differences were measured with the paired Student's t-tests.

Results indicated that after 1 month, 73 participants returned and after 6 months, 13 did not return. After 1 month, 33% of the participants were using the

Provox FreeHands HME® on a daily basis; after 6 months, 19% were using it on a daily basis, 57% were using it for special occasions and 24% stopped using it altogether. At 1 month, various voice measures were rated as good. At 6 months, they were rated as fair. However, the overall rating was still good, revealing that there was no change in voice quality over time. Perceptive evaluation revealed no statistical difference between the three stoma occlusions. No significant difference in any of the acoustic measurements between 1 and 6 months were noted. The Provox HME® demonstrated significantly better results for all the acoustic measurements. There were no statistically significant changes in QOL overtime.

A large majority of the participants in this study (2/3) were using the hands-free device after 6 months, signifying the importance of this research. Although no improvements in voice measures were made evident in this study (compared to Provox HME®), the researchers suggested that improvements in adhesion could increase success rate. Overall, methods were described in sufficient detail except for randomization of perceptual assessments and randomization of occlusion method used in acoustic analysis. Upon last assessment, a total of 18 participants did not return to the study and not all participants complied with the tasks due to fatigue or fixation problems. The researchers describe some limitations, including lack of a definition of "everyday use" for the Provox FreeHands HME®. This study presents a level II statistical evidence and due to a large sample size and excellent methodological detail, the results in this study are suggestive.

Tervonen et al. (2005) compared the Provox FreeHands HME® with the Provox HME®. Fourteen laryngectomized males between to 1995 and 2002 were chosen for the study. Because Hilgers et al. (2003) reported more air pressure needed for speech and that breathing was heavier with the Provox FreeHands HME®, the researcher controlled for HME users by only selecting participants who used HMEs successfully.

Structured questionnaires (free-text and Visual Analog Scales) on voicing and breathing, skin adhesion and subjective voice quality were given. MPT and dynamic range were recorded, as well as perceptual evaluation by 5 speech pathologists that were blinded to the type of device. Health related QOL was measured with a 15D scale that was compared with age and sex matched population.

Two-way analysis of variance, paired sample test and Wilcoxon's test were used for statistical analysis. The Mann-Whitney test served to compare the 15D with the general population. Based on the questionnaire, the Provox FreeHands HME® made breathing heavier in 64% of the participants, speaking more difficult in 50% and worse voice quality in 29%. Despite the problems, individuals found it useful and easy to use. Phonation was highest with the Provox FreeHands HME® whereas intelligibility and usefulness was better with HME only. QOL was not reduced with the Provox FreeHands HME®.

This repeated measures design renders a level II statistical evidence. Although the authors mentioned their design as being a cohort, it is assumed that their definition of cohort refers to their inclusion criteria (participants between 1995 and 2002 who were laryngectomized). No comparison group was used in the study, except for comparing QOL to a general population. One limitation was the small sample size. In addition, validity and reliability of the questionnaire was not discussed, nor was the randomization of occlusion type (i.e., order effect) or the time period after the Provox FreeHands HME® was given. Given the multiple limitations to the study, the evidence for the Provox FreeHands HME® is equivocal.

Hamade et al. (2006) utilized a within subject design to compare acoustical and perceptual analysis between the Provox FreeHands HME® and the Provox HME ® in 4 males with no previous experience. Each subject received both treatments and received a 4 week familiarization period with the new device. Each individual made two randomized acoustic recordings (one for each device) completed a questionnaire and kept a diary. The acoustic recordings included: three sustained /a/ for 5 seconds, reading of the first two paragraphs of the Rainbow Passage, counting from one to ten and three trials of MPT. Harmonics-to-noise ratio (HNR) and extraneous noise were considered. The questionnaire targeted information regarding removal of the device, level of spontaneous speech, voice quality, QOL, future use and advantages and disadvantages; notable themes were identified. The diaries elicited information regarding duration of base-plate seals over a period of 7 days.

Level II experimental evidence was used in this study. The Wilcoxon Signed Ranks was used to test for significant acoustical differences between the two occlusion types. Results obtained included significant increase in mean intensity of inhalation noise, lowered MPT and significantly reduced mean

intensity during reading with the Provox FreeHands HME®. The Provox FreeHands HME® valve was "a little more difficult" to insert for all participants; however, all participants agreed that the Provox FreeHands HME® improved their quality of life. Disadvantages included cleaning the device and increased effort involved with insertion and removal. All participants agreed the freedom to use their hands while talking and the more normal appearance during speech were the most advantageous aspect of the hands-free device. Only three diaries were returned and revealed that seal time was shorter for automatic occlusion.

There were statistically significant changes in acoustical measures from the Provox FreeHands HME® and Provox HME®; however, due to a small sample size, lack of methodological detail, lack of randomization of occlusion method and limited information on the questionnaire, it is difficult to render this study as suggestive. However, the idea behind using a hands-free mode of speech is shown to be important to laryngectomized individuals and therefore warrants further research into improving hands-free devices for these individuals.

Lorenz et al. (2007) performed a within subject design looking at 17 laryngectomized individuals (21 males, 3 females) who had no previous experience with other tracheostoma valves. The participants received 2 hours of training and after 4 weeks and 6 months, the participants were asked to complete a standardized, study-specific questionnaire and subjectively evaluate voice quality, wearing comfort, fixation, potential problems and efficiency of the Provox FreeHands HME®. Additionally, after 4 weeks and 6 months, subjects were assessed on voice quality for the three different devices (e.g., dynamic ranges, frequency, MPT, number of breaths, number of syllables/breath, etc). Each participant performed the telephone intelligibility test three times and a phonetician evaluated voice quality.

Data was measured on the strength of association using the Pearson's correlation coefficient and a paired Student's t-test for comparing the different methods of occlusion. Results suggested that 42% of the participants reported that they used the Provox FreeHands HME® every day. The remaining individuals reported that they did not use the valve on a regular basis because of skin irritation, effortful speech and difficulty inserting the valve. Almost 89% of the participants agreed that it was an advantage to speak with their hands and 74% noted that the Provox FreeHands HME® decreased their level of disability. The Provox FreeHands HME®'s acoustic results were comparable to digital occlusion and HME only, however, lower. Voice quality was found to be *good* in 15 participants and *moderate* in 2.

Level II evidence was obtained from this study. However, this study has many limitations that make it difficult to interpret the findings as compelling. Some limitations include: small sample size, participant withdrawal, lack of information on questionnaire and lack of information on randomization. Additionally, although voice quality was judged to be "good", it is unclear whether the judge was blinded to which occlusion method.

Discussion

A review of the studies pertaining to the new Provox FreeHands HME® suggests that generally, individuals prefer using the hands-free device because it minimizes their disability and allows them to use their hands while conversing, despite the associated disadvantages. However, weaknesses in methodology, small sample size and lack of information on reliability and validity of questionnaires reduce the strength of evidence.

Quality of Life

Some studies found no statistical differences in QOL. Due to the lack of information of tests used (i.e., standardization, validity, etc) in the aforementioned studies, it is uncertain whether the Provox FreeHands HME® actually had an effect on QOL. However, even despite the shortcomings participants encountered with the new device, many participants claimed it helped with QOL by reducing their disability and allowing them to have a more normal appearance.

Compliance

Approximately half of the participants in most studies used the hands-free device everyday. Generally, compliance was decreased due to adhesion and irritation to skin, increased inhalation noise and difficulty inserting the valve.

Voice Quality

Overall, the Provox HME® performed better on acoustical measurements; however, two studies did result in higher mean intensity with the Provox FreeHands HME®. Additionally, the Provox FreeHands HME® performed better than the Blom-Singer ATV®. No perceptual differences were reported between any of the occlusion methods. No acoustical characteristics changed over time with the Provox FreeHands HME®. Heavier breathing was observed in many participants using the Provox

FreeHands HME®, which could be due to the increased pressure needed to close the hands-free valve.

These results have implications for S-LPs in clinical practice for the reason that clinicians must be aware of the available hands-free devices and their effects on individuals who use them. Gerwin and Culton (1993) suggest that tracheoesophageal prosthesis (TEP) success is greater when "patients are prepared, motivated, educated, and their psychological idiosyncrasies are attended to" (p. 438). It is necessary to continue with this research to provide individuals with the most accurate information possible. The idea behind using a hands-free mode of speech is shown to be of importance to laryngectomized individuals and therefore warrants further research into improving hands-free devices.

Recommendations

Future research should focus on the following in order to provide more compelling evidence:

- Clear identification and/or implementation of blinding procedures for examiners and subjects in order to increase the reliability of the results.
- Considering the small head and neck population, increasing sample size to implement more compelling evidence would be beneficial.
- Because of the uniqueness of this population, one might perform a single-subject design to increase experimental evidence and provide the most valid and clinically relevant results.
- Sufficient data regarding the procedure used must be included to allow the study to be replicated.
- Use of suitable questionnaires, along with identifying what these assessment measures are and indicating their validity and reliability.
- Further comparison of other brands of hands-free devices to the Provox FreeHands HME®.
- Many studies discussed neck seal as a major disadvantage to the Provox FreeHands HME®; further adjustment/development of the adhesion used in hands-free devices.
- More research needed for the effect of this device on QOL.

Clinical Implications

Although some of the results from the above studies are not in agreement, there are commonalities of clinical importance that clinicians should consider when providing options for this unique population.

- Complete and accurate information must be given to individuals seeking alaryngeal methods of speech. This includes discussion of all methods of alaryngeal speech (e.g., electrolarynx, TEP, esophageal speech).
- Each patient is unique; quality of life may be different for each patient and may also vary within that patient.
- The studies did highlight the importance of gestures during communication and the need to feel socially accepted and not be regarded as 'disabled'. It is important to give the patient as much locus of control by providing information so they are able to make informed decisions about their communication options.
- The Provox FreeHands HME® may be the most beneficial for individuals who require or prefer to use their hands while speaking (e.g., social gatherings, professional speakers, teachers, etc).

This population is unique in the sense that there is great variability within and between individuals' quality of life and as clinicians, having the ability to show our patients a device that can potential improve QOL is invaluable. It is imperative that speech-language pathologists partake in the assessment and management of individuals with a laryngectomy with knowledge of the existing literature related to voice quality, quality of life and compliance of each alaryngeal device. With this knowledge, the speech-language pathologist enables each patient to make a complete informed decision regarding his or her ability to communicate.

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