Review

Folia Phoniatrica et Logopaedica

Folia Phoniatr Logop 2016;68:282–289 DOI: 10.1159/000484715 Published online: December 12, 2017

Evaluation of Direct and Indirect Methods of Sub-Neoglottic Pressure Measurement in Tracheoesophageal Speakers: A Systematic Review and Meta-Analysis

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Keywords

Sub-neoglottic pressure \cdot Tracheoesophageal speech \cdot Voice prosthesis \cdot Systematic review

Abstract

Objective: Tracheoesophageal (TE) prosthetic voice is one of the voice restoration options for individuals who have undergone a total laryngectomy. Aerodynamic analysis of the TE voice provides insight into the physiological changes that occur at the level of the neoglottis with voice prosthesis in situ. The present study is a systematic review and meta-analysis of sub-neoglottic pressure (SNP) measurement in TE speakers by direct and indirect methods. Patients and Methods: The screening of abstracts and titles was carried out for inclusion of articles using 10 electronic databases spanning the period from 1979 to 2016. Ten articles which met the inclusion criteria were considered for meta-analysis with a pooled age range of 40-83 years. Results: The pooled mean SNP obtained from the direct measurement method was 53.80 cm H₂O with a 95% confidence interval of 21.14–86.46 cm H₂O, while for the indirect measurement method, the mean SNP was 23.55 cm H₂O with a 95% confidence interval of 19.23–27.87 cm H₂O. Conclusion: Based on the literature

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E-Mail karger@karger.com www.karger.com/fpl review, the various procedures followed for direct and indirect measurements of SNP contributed to a range of differences in outcome measures. The meta-analysis revealed that the "interpolation method" for indirect estimation of SNP was the most acceptable and valid method in TE speakers. © 2017 S. Karger AG, Basel

Introduction

Laryngeal aerodynamics deals with the measurement of airflow and pressure produced by laryngeal voice production [1]. It is considered an essential tool for clinical voice evaluation [2]. Tracheoesophageal (TE) prosthetic voice is one of the most preferred alaryngeal voice restoration options for individuals who have undergone a total laryngectomy [3]. Air from the lungs is shunted into the esophagus via the one-way valve of the voice prosthesis to vibrate the pharyngoesophageal (PE) segment to produce voice.

Aerodynamic analysis of TE voice can provide insight into the physiological changes at the level of the PE segment (also called neoglottis) with the prosthesis in situ. In other words, it is presumed to provide a perspective as to the neoglottic valving efficiency of voicing. Some of these aerodynamic measures are maximum phonation duration, s/z ratio, sub-neoglottic pressure (SNP, cm H_2O), mean airflow rate (L/s), neoglottic airway resistance (cm $H_2O/L/s$), and neoglottic airway conductance (L/s/cm H_2O).

SNP is an important aerodynamic measure in voicing. The SNP is the air pressure below the PE segment developed by the respiratory system for TE speech production [4]. Similar to subglottal pressure (SGP), SNP can be commonly measured in cm H₂O [1] using direct and indirect methods. In the direct method, one of the procedures involves measurement by placing a hypodermic needle into the tracheostoma in the anterior neck. The needle is externally connected to a pressure transducer by a thin, relatively short piece of polyethylene tubing to measure SNP [5]. The second method involves placing a miniaturized pressure transducer in the neoglottis through the nostril [6] and making the measurement. Among indirect methods, the "intraesophageal pressure balloon" method involves inserting a deflated balloonlike device connected to a catheter tube transnasally into the esophagus at the mid-thoracic level. The catheter is connected to a pressure transducer and the balloon is slightly inflated. The intratracheal pressure (cm H_2O) (approximately equal to SGP) is transmitted to the balloon via the posterior tracheal wall, which is attached to the anterior esophageal wall [7-9].

In each of the methods described above, the procedures are more or less invasive, and for routine practice in clinical settings, a method needs to be simple and noninvasive. There are two indirect, noninvasive methods available and desirable. The "airway interruption method" [10] is based on the air pressure in the airway during the sudden interruption of vowel sound production. In this procedure, repeated syllables of /pi/ are used to estimate the SGP during the vowel segment /i/ between the consonants at a constant pitch and at a rate of 1.5 syllables per second. During the production of /i/, the vocal folds are vibrating, the lips are open, and intraoral pressure (IOP) is equal to the atmospheric pressure. Before the release of the plosive /p/, the lips are closed, the vocal cords are open, and SGP and IOP are equal. In the second method, referred to as the "interpolation method" [11], estimation is based upon the peak IOP during production of /p/ surrounded by vowels. The pressure measurement directly indicates the power of the air supply to the phonatory mechanism. The stronger the air supply, the higher the pressure values [4].

Table 1. "Keywords" used to identify the primary studies

- #1 "Direct method", "Direct methodology", "Direct evaluation", "Direct calculation", "Direct measurement"
- #2 "Indirect method", "Indirect methodology", "Indirect evaluation", "Indirect calculation", "Indirect measurement"
- #3 "Sub-neoglottic pressure", "Tracheal pressure",
 "Endotracheal pressure", "Endo-tracheal pressure",
 "Intratracheal pressure", "Intra-tracheal pressure",
 "Esophageal pressure", "Endoesophageal Pressure",
 "Endo-esophageal Pressure", "Intraesophageal pressure",
 "Intra-esophageal pressure", "Subpseudoglottic pressure",
 "Sub-pseudoglottic pressure", "Sub-pseudo-glottic pressure",
 "Sub-neoglottal pressure", "Intraoral pressure", "Intra-oral pressure", "Articulatory pressure"
- #4 "Tracheo-esophageal speakers", "Tracheoesophageal speakers", "Tracheoesophageal prosthetic voice users", "Tracheoesophageal voice speakers", "Tracheoesophageal speech users", "Tracheoesophageal voice prosthesis users", "Tracheoesophageal voice prosthesis speakers", "Voice prosthesis users", "Voice prosthesis speakers", "Voice prosthesis users", "Voice prosthesis speakers", "Tracheo-esophageal puncture speakers", "Tracheoesophageal puncture users", "Speech prosthesis users"

Need for the Study

Subsequent to total laryngectomy, patients exhibit differences in the anatomical and functional aspects of their respiratory, phonatory, and digestive systems. The innate function of the PE segment is to maintain tonicity of the cricopharyngeal muscle, thereby preventing gastroesophageal reflux [12]. Individuals who have undergone a total laryngectomy depend on the PE segment for voice production. Aerodynamic analysis of subsequent voice production captures the relation between respiratory and laryngeal system functions during TE voice production. Unlike the true vocal folds, the PE segment has a very different vibrating mechanism principle for voice production. The mass, length, and tension of the true vocal folds can be manipulated in normal laryngeal speakers, while the PE segment is under little voluntary control [13]. The vibration of the tonic PE segment needs more pressure for producing sound than that required for phonation with the true vocal folds [14]. This warrants the need to consider SNP (cm H₂O) as a standard objective measure in prosthetic aided voice rehabilitation.

Several studies have pointed out the accuracy of estimation method of SNP measurement for clinical and research purposes [15–17]. The accuracy of the indirect

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Quality assessment criteria		Reference number								
	20	21	22 ^a	23	24	25	26	4	27	28
Clear presentation of design	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Appropriate design	Υ	Υ	Y	Y	Y	Y	Y	Υ	Y	Υ
Appropriate inclusionary and exclusionary criteria	Υ	Υ	Y	Y	Υ	Y	Y	Υ	Y	Y
Appropriate experimental methods	Y	Υ	Y	Y	Υ	Y	Y	Υ	Y	Υ
Clear outcome measures	Υ	Υ	Y	Y	Y	Y	Y	Υ	Y	Υ
Appropriate outcome measures	Υ	Υ	Y	Y	Y	Y	Y	Υ	Y	Υ
Measurement of interrater reliability	Ν	Ν	Ν	Ν	Ν	Ν	Ν	Ν	Ν	Ν
Adherence to protocol	Υ	Υ	Y	Y	Υ	Y	Y	Υ	Y	Υ
Clear data analysis	Υ	Y	Y	Y	Υ	Y	Y	Υ	Y	Υ
Appropriate data analysis	Y	Υ	Y	Υ	Y	Y	Y	Y	Y	Y

Adopted from Leydon et al. [25], 2010, and Berman and Parker [26], 2002. Y, yes; N, no. ^a Study comprises both direct and indirect measurement methods of SNP (cm H_2O) findings.

method of estimating SGP (cm H_2O) has been reported in normal laryngeal speakers [18–20], individuals with vocal fold paralysis, and individuals who have undergone a partial laryngectomy [21]. Those studies compared the direct and indirect SGP (cm H_2O) measurement methods and reported minimal differences between them. However, in TE speakers, there is a paucity of information regarding SNP (cm H_2O) in direct and indirect measurement methods. The current systematic review and metaanalysis provides information on various methods used in the direct and indirect estimation of SNP in the clinical evaluation of TE voice. The information obtained from this review should contribute to the knowledge of clinicians working with this population.

Methods

Study Selection Criteria

Published studies involving only original data that satisfied the following criteria were considered: (1) SNP (cm H_2O) should be the target parameter measured, (2) both male and/or female TE speakers aged 18 years and older were considered, (3) studies with the objective of measuring SNP (cm H_2O) using direct and/or indirect methods at a comfortable pitch and loudness were permitted, and (4) the measured parameters of all the studies had to include a mean and standard deviation of SNP (cm H_2O). The rationale behind this criterion was to provide the pooled mean and confidence interval (CI) at a comfortable pitch and loudness level specific to evaluation methods following meta-analysis. In addition, studies involving all types of research study designs were included. Aerodynamic studies performed in vitro and other alaryngeal voice restoration modes (esophageal speech, artificial larynx, gastric speech, buccal speech, and ASAI speech) were excluded.

Search Strategy

The literature search strategy followed the PICO Model, where P (Population of interest) is tracheoesophageal speakers, I (Intervention) is not applicable, C (Comparison) is between evaluation of direct and indirect methods, and O (Outcome) is SNP measurement. Cochrane collaboration [22] and preferred reporting items for systematic review and meta-analyses (PRISMA) guidelines [23] were followed to carry out the study. Electronic databases such as Cochrane Central Register of Control Trials (CENTRAL), Cumulative Index to Nursing and Allied Health Literature (CINHAL), Educational Resources and Information Centre (ERIC), IndMED, Ovid SP, ProQuest Medical Library, PubMed/Medline, Science Direct, Scopus, and Web of Science were used for the title, abstract, and fulltext screening by 2 independent reviewers (S.S. and V.U.A.). Using a systematic search, articles published between 1950 and 2016 were identified and reviewed. Though the first voice prosthesis was commercially available during 1979 [24], the search filter in the current study was set at "1950" to rule out any preliminary research undertaken related to voice prostheses. A combination of keywords (Table 1) was used to identify the primary studies. These keywords were used to develop search strings as per the requirements of the databases using Boolean operators (AND, OR). Following title and abstract screening, full-text version of those studies meeting the inclusion criteria were reviewed (S.S. and V.U.A.). Manual search of various journals did not provide any additional relevant studies (S.S. and B.R.). In total, 10 studies were included in the meta-analysis.

Data Extraction and Management

Two studies were identified that used a direct method of measuring SNP (cm H_2O), and 7 used an indirect method. There was 1 study with both measurement methods. Therefore, the count for the direct measurement method was 3 and the count for the indirect measurement method was 8. SNP values were converted to a common measurement unit (i.e., cm H_2O) for direct comparison across studies (S.S. and V.U.A.). The data extracted from the studies included name of author(s), year of publication, sample size, and mean and standard deviation of SNP (cm H_2O) and were or-

Authors [Ref.], year	Study design/Participants/Age range/ Inclusion criteria	Type of direct method/instrument used	Type of task	
Moon and Weinberg [29], 1987	Cross-sectional study design n = 5, (3 male, 2 female); 45–63 years Inclusion criteria: TE speech as the primary method of communication Use of tracheostoma valve at the time of the experiment 2 subjects: Bivona low resistance, 2 subjects: 20-Fr home-made prototype by Blom; 1 subject Blom-Singer duck bill	Intratracheal pressure method Insertion of 14-G hypodermic needle in the trachea through a modified (slightly extended) tracheostomal breathing valve housing connected to differential pressure transducer (Setra Model 239E pressure transducer), amplified and low-pass filtered at 100 Hz (Accudata model 109 DC amplifier), and recorded on a sound channel of the FM tape recorder Pressure measurement system calibration using U-tube water manometer	Sustained vowel /a/	
Schutte and Nieboer [28], 2002	Cross-sectional study design <i>n</i> = 18; 40–83 years (mean 62.3 years) Inclusion criteria: all TE speakers with Groningen voice prosthesis	Intatracheal pressure method Open polyethylene catheter (outside diameter, 2.0 mm; inside diameter, 1.4 mm; length, 1.4 m) was inserted into the tracheostoma and was held by the patient him/herself under digital occlusion of the tracheostoma. The proximal end of the catheter was connected to a differential pressure transducer (Hewlett Packard 267 BC) coupled to a carrier amplifier (Hewlett Packard 8805B) Pressure measuring system calibration was done using a U-shaped water manometer	Sustained vowel /a/	
Grolman et al. [27], 2007	Cross-sectional study design n = 8 Inclusion criteria: all TE speakers had to be tracheostoma valve users in daily life	Intratracheal pressure method The calibrated pressure transducer (Setra System Inc., Action, MA, USA) was connected to the tracheostoma using a modified Blom-Singer tracheostoma valve housing	Sustained vowel /a/	

Table 3. Studies included for the systematic review and meta-analysis of direct measurement methods of SNP (cm H₂O) in TE speakers

ganized into a data extraction sheet. For all TE speakers, the ages across studies ranged from 40 to 83 years. As all the data required to answer the study questions have been published within research articles, no communication with authors was considered necessary. Quality assessment of the articles was completed using an assessment survey (Table 2) adopted from an earlier systematic review and meta-analysis [25, 26]. Two blinded raters were included for the evaluation of the methodological quality of the studies. A third rater served as an arbiter when disagreements occurred.

Statistical Analysis

Pooled mean and 95% CI were computed for SNP (cm H₂O). "Stata 13" statistical software was used for meta-analysis. Analysis was carried out with the assumption of a "random effect model" providing a more representative estimate than a fixed effect model. Heterogeneity was assessed using χ^2 Q statistics and heterogeneity index I^2 (M.G.L.).

Results

Tables 3 and 4 present the details of the studies included in the current review of direct and indirect measurement methods of SNP (cm H_2O) in TE speakers. The pooled means of SNP (cm H_2O), CI, Q, and I^2 values were obtained from direct and indirect measurement methods in TE speakers. Three studies with a sample size of 31 qualified for meta-analysis of SNP (cm H₂O) obtained from the direct measurement method. The pooled mean was 53.80 cm H₂O with a 95% CI of 21.14–86.46 cm H₂O. There was a significant moderate heterogeneity in the results ($I^2 = 96.9 \%$, $p \le 0.01$). The forest plot of SNP cm H₂O obtained from the direct method is shown in Figure 1.

Eight studies with a sample size of 66 qualified for meta-analysis of SNP (cm H₂O) obtained from the indirect method. The pooled mean was 23.55 cm H₂O with a 95% CI of 19.23–27.87 cm H₂O. There was high heterogeneity in the results ($I^2 = 88.05 \%$, $p \le 0.01$). The forest plot of SNP (cm H₂O) obtained from the indirect measurement method is shown in Figure 2.

Discussion

SNP has been accepted as an important aerodynamic measure to understand the vibratory characteristics of the PE segment. An accurate measure of SNP enhances the

Authors [Ref.], year	Study design/Participants/ Inclusion criteria	Type of indirect method/instrument used	Type of task Sustained vowel /a/	
Weinberg et al. [13], 1982	Cross-sectional study design $n = 18$; male Inclusion criteria: all TE speakers with Blom-Singer voice prosthesis	Intraesophageal pressure method Catheter assembly was inserted into the base of voice prosthesis, which was connected to the pressure transducer (Statham PM197) Pressure measuring system calibration was done using a U-shaped water manometer		
Motta et al. [30], 2001	Cross-sectional study design <i>n</i> = 6; male Inclusion criteria: all TE speakers with Bivona-Colorado low-resistance voice prosthesis (Bivona Medical Technologies, Gary, IN, USA)	Interpolation method Aerophone II (F.J. Electronics, Copenhagen, Denmark) Pressure transducer calibration was done	/pi/ syllable repetition	
Eksteen et al. [31], 2003	Cross-sectional study design <i>n</i> = 6; male; 49–68 years (mean 61 years) Inclusion criteria: TE speakers	Interpolation method PERCI-SARS (Microtronics Corporation, 1999, Chapel Hill, NC, USA)	/pi/ syllable repetition	
Grolman et al. [27], 2007	Cross-sectional study design n = 8 Inclusion criteria: all TE speakers had to be tracheostoma valve users in daily life	Intraesophageal pressure method It was measured by a mikro-Tip pressure transducer (Millar Instruments, Houston, TX, USA) positioned at voice prosthesis in the esophagus Calibration of sensors was done	Sustained vowel /a/	
Kotby et al. [34], 2009	Cross-sectional study design <i>n</i> = 18; male Inclusion criteria: TE speakers	Intraesophageal pressure method A tube (inside diameter, 3 mm; outside diameter, 4.1 mm) was passed through the nasal cavity and introduced into the upper esophagus, and secured at a distance of 15 cm from the upper central incisors The other end of the tube was connected to the oral pressure input of the PERCI-SARS apparatus	Sustained vowel /a/	
Ng [4], 2001	Cross-sectional study design n = 12; male Inclusion criteria: TE speakers	Interpolation method Airflow and air pressure transduction system (MS-110, Glottal Enterprises, Syracuse, NY, USA)	/p ^h i/ syllable repetition	
Bohnenkamp et al. [33], 2011	Cross-sectional study design n = 5; male; 50–81 years (mean 61.20, SD 11.05 years) Inclusion criteria: TE speakers with Blom-Singer voice prosthesis	= 5; male; 50-81 years (meanPressure signals (model MA-IL, Glottal Enterprises)1.20, SD 11.05 years)were transduced and amplified (model MS100S, Glottalaclusion criteria: TE speakers withEnterprises) after calibration (MCU-4, Glottal Enterprises)hom-Singer voice prosthesisThe pressure and flow signals were processed through		
Bohnenkamp et al. [32], 2012	Cross-sectional study design n = 6; male; 50–81 years (mean 62.1, SD 10.28 years) Inclusion criteria: TE speakers with Blom-Singer voice prosthesis	wideband and low-frequency transducers (PTW-2, Glottal Enterprises) Speech and oral air pressure was low-pass filtered (cutoff frequency, 9 kHz) and sampled at 22 kHz by use of the time-frequent analysis 32-bit (TF32) aeros analysis software		

Table 4. Studies included for the systematic review and meta-analysis of indirect measurement methods of SNP (cm H₂O) in TE speakers

objectivity in evaluation of TE voice and subsequently aids in planning voice therapy for this population. Results of the current review found the pooled mean of SNP (cm H_2O) determined from the direct method to be greater

than that determined from the indirect method. In TE speakers, the intratracheal pressure was measured by placing a polyethylene catheter into the tracheostoma with the proximal end connected to a differential pressure

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Authors [Ref.], year	Parti n	cipants,			Mean ESNP, cm H ₂ O (95% CI)	Weight, %
Moon and Weinberg [29], 1987	5	+			30.09 (20.05, 40.13)	33.63
Schutte and Nieboer [28], 2002	18			→	100.95 (84.93, 116.97)	32.05
Grolman et al. [27], 2007	8				33.00 (26.97, 39.03)	34.32
Overall ($l^2 = 96.9\%$, $p = 0.000$)		\langle		>	53.80 (21.14, 86.46)	100.00
	0	20 40	60 80	100		

Fig. 1. Forest plot of SNP (cm H_2O) obtained from the direct measurement method in TE speakers. Note: weights are from random-effects analysis.

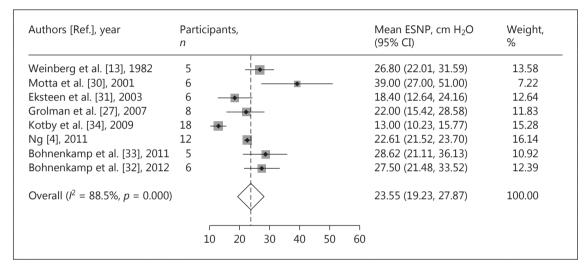


Fig. 2. Forest plot of SNP (cm H_2O) obtained from the indirect measurement method in TE speakers. Note: weights are from random-effects analysis.

transducer to determine SNP (cm H_2O). The measured pressure value reflects the summation of SNP (cm H_2O) and the pressure drop across the voice prosthesis [27, 28]. In TE speakers, it has been stated that measuring the intratracheal pressure using the above procedure would help in measuring the transprosthesis pressure [27]. Hence, the direct estimation of SNP (cm H_2O) using the intratracheal method has yielded higher pressure values in TE speakers, which is not a valid representation of SNP (cm H_2O). Among studies considered [27–29], it was observed that there was (1) no mention of the voice prosthesis type [27], (2) mention of a particular type [28], or (3) mention of different types of voice prosthesis with respect to 5 participants considered in a study [29] (Table 3). Therefore, meta-analysis was limited to the type of measurement methods used. Further research with respect to voice prosthesis type details are required to quantify the transprosthesis pressure differences.

SNP (cm H_2O) obtained from determining the tracheal pressure by inserting a hypodermic needle through a stoma valve into the trachea is difficult to compare with the SNP (cm H_2O) obtained by the indirect method using esophageal pressure in which a tube-balloon unit is placed at the upper esophagus via the nose. This is due to the tracheal pressure reflecting the influence of the TE voice source (PE segment) along with the voice prosthesis. However, these two components are presumed to form the integral parts of TE voice production [29]. Studies us-

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ing normal laryngeal speakers through the use of the drop in intraesophageal pressure, which results when phonation is interrupted with the vocal fold abducted and lung volume held constant, are considered to provide a valid estimate of SGP under conditions of sustained phonation [5].

SNP (cm H_2O) values obtained from the indirect measurement such as the interpolation method [4, 30–33] probably depend on the proper recording methodology and analysis of the IOP in TE speakers. It is appropriate to recall the reports of SGP (cm H_2O) estimated from the IOP (cm H_2O) in normal laryngeal speakers, which clearly indicated that the syllable string, syllable rate, lip closed quotient, loudness, pitch, articulation, oral pressure signal type, location on oral pressure signal used to estimate SGP (cm H_2O), equipment calibration, and frequency response are the factors to be considered [17].

On observation of the forest plot of SNP (cm H₂O) measured from the direct method (Fig. 1), a wider CI width of 21.14–86.46 cm H₂O was observed for the pooled mean of SNP (cm H₂O). This can be attributed to the difference in sample size, in turn revealing moderate heterogeneity ($I^2 = 96.9\%$). Among the 3 studies considered for the pooling of the SNP (cm H₂O) measured from the direct method, 2 studies [28, 29] had smaller sample sizes, but the study with the larger sample size [28] could have contributed to the wider CI width. As a result, the overall CI width at the 95% level was observed to be wider indicating a larger distance from the pooled mean.

Based on observation of the forest plot of SNP (cm H_2O) measured from the indirect method (Fig. 2), a majority of the studies intersected at the pooled estimate line indicating lesser variation from the estimated pooled mean (23.55 cm H_2O). Further, a narrower CI width (19.23–27.87 cm H_2O) for the overall pooled mean of SNP (cm H_2O) revealed the consistency in the measured mean values across the studies, in spite of differences in the measurement procedures adopted in the indirect methods. However, 5 out of 8 studies [4, 30–33] using the interpolation method and 2 studies [27, 34] using the intraesophageal method should not be overlooked.

The current meta-analysis identified a substantial difference between the pooled means of SNP (cm H_2O) obtained from direct and indirect measurement methods in TE speakers and SGP in normal laryngeal speakers [18, 19, 21]. This difference can be due to changes in the respiratory system (reduced vital capacity; functional residual capacity, and mean expiratory flow rate), change in source of vibration (glottis to neoglottis) following total laryngectomy, change in vibrating principles (mass, length, and tension), and respiratory compromise due to typical age-related changes (loss of elasticity; recoil forces and reduced muscular forces) [14, 35–42]. Hence, SNP values obtained from the direct and indirect measurement methods in TE speakers may not be comparable with SGP obtained from normal laryngeal speakers. However, this difference needs to be further explained and confirmed with more comparative studies.

Conclusion

Measurement of SNP (cm H_2O) is essential to understand the aerodynamic aspects of TE speech. The current meta-analysis suggests that SNP (cm H_2O) values obtained from the direct measurement cannot be compared with those obtained from the indirect measurement method in TE speakers. Further, it was revealed that the interpolation method for the indirect estimation of SNP (cm H_2O) is the most acceptable and valid method in TE speakers. This information should be useful to speechlanguage pathologists in the management of TE speakers for optimal voice quality outcomes.

Acknowledgement

Sincere thanks to Cancer Aid and Research Foundation (CARF) and Prof. Bellur Rajashekhar, Chair in Head and Neck Cancer Research and Voice Restoration, Manipal Academy of Higher Education, India, for funding support.

Disclosure Statement

The authors have no conflict of interest to declare.

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