

The research questions and methodological adequacy of clinical studies of the voice and larynx published in Brazilian and international journals

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Abstract

Objective To evaluate the methodological adequacy of voice and laryngeal study designs published in speech-language pathology and otorhinolaryngology journals indexed for the ISI Web of Knowledge® (ISI® Web) and the MEDLINE® database.

Methods A cross-sectional study conducted at the Universidade Federal de São Paulo (Federal University of São Paulo). Two Brazilian speech-language pathology and otorhinolaryngology journals (Pró-Fono and Revista Brasileira de Otorrinolaringologia) and two international speech-language pathology and otorhinolaryngology journals (Journal of Voice, Laryngoscope), all dated between 2000 and 2004, were hand-searched by specialists. Subsequently, voice and larynx publications were separated, and a speech-language pathologist and otorhinolaryngologist classified 374 articles from the four journals according to objective and study design.

Results The predominant objective contained in the articles was that of primary diagnostic evaluation (27%), and the most frequent study design was case series (33.7%). A mere 7.8% of the studies were designed adequately with respect to the stated objectives. There was no statistical difference in the methodological quality of studies indexed for the ISI® Web and the MEDLINE® database.

Conclusion The studies published in both national journals, indexed for the MEDLINE® database, and international journals, indexed for the ISI® Web, demonstrate weak methodology, with research poorly designed to meet the proposed objectives. There is much scientific work to be done in order to decrease uncertainty in the field analysed.

Introduction

The best known scientific research databases available on the Internet offer health professionals an enormous amount of information to aid decision making vis-à-vis their patients. Information analysis for proper decision making is a fundamental process for professionals, and thus, they must ensure that their clinical actions are up-to-date, consistent with available human and technological resources and in accordance with patients' wishes. In this day and age, given the Internet's excellent guiding role, patients now arrive at health professionals' offices better informed and more demanding than ever before. Nevertheless, the variety of sources for

medical literature places heavy demands on researchers' and/or professionals' time and is frequently the cause of confusion.

Clinical decisions must be based on personal experience and on information from books and publications in scientific journals. Nevertheless, the mere availability of a large quantity of information does not speak to the quality thereof. In practice, the sheer quantity of information has become a great hurdle for the researcher who needs to know first which studies are relevant and which encompass an adequate scientific gauge by which he/she should do his/her actions. Given this scenario, merely researching available sources proves insufficient; indeed, it is necessary to know or to choose, via established criteria, which material should

be consulted or which should be developed further in order to respond to unanswered (or under-answered) questions.

In the attempt to reconcile the problem of information quantity with information quality, the epidemiological method was adopted in clinical practice a few years ago. This method equips researchers with mathematical and statistical bases to prevent biased methodology. Moreover, it reduces the time spent researching and leads to more objective and reliable conclusions.

This new practice is rendered as the conscientious, explicit and judicious use of the best evidence available for making individual patient health care decisions [1]. In addition, it lends itself to combining the best evidence gleaned from clinical research with practical experience and with the patients' best expectations [2].

To a certain extent, 'this concept of science discourages practice based merely on intuition, on non-systematized clinical experience and on psychopathological theories; indeed, it emphasizes a refined methodological analysis, development of better research designs, better implementation of said designs and statistical analysis. Being thus, this conception of science is complemented by well-defined critical-assessment methods and systematic reviews of medical literature.' [3].

Research in voice and larynx conducted by speech-language pathologists and otorhinolaryngologists have also demonstrated noticeable growth in terms of the quantity of scientific material published. One of the primary factors for this growth has been the development of new imaging and sound equipment that allow for more precise and objective treatments.

Given the foregoing, speech-language pathologists' and otorhinolaryngologists' scientific research should advance in consideration of the objective to refine research methodology, expanding the quantity of scientifically adequate and thorough material. Such research should be conducted in a manner that is adequate vis-à-vis development of the research objective.

Indeed, certain research designs are more adequate for certain questions, the design being the process whereby the most ample conceptual hypothesis becomes the most prudent operational hypothesis [4]. For each question or objective, the study design must be the best suited for the question posited [5].

Objective

The objective of this research is to assess the methodological adequacy of study designs concerning the voice and larynx published in two Brazilian journals, indexed for the MEDLINE® database, and to international journals, indexed for the ISI® Web and MEDLINE® database.

Methods

This study was conducted under the auspices of the Department of Emergency Medicine at the Universidade Federal de São Paulo [Federal University of São Paulo (UNIFESP)], as part of the Graduate Program in Internal and Therapeutic Medicine, in conjunction with The Brazilian Cochrane Center.

This study was approved by the Ethical Research Committee of the UNIFESP and is comprised of the following three stages:

- 1 election of journals included in study;
- 2 selection of articles on voice and larynx published in selected journals, and
- 3 assessment and classification of said articles.

Table 1 Number of articles published in 5 years, number of articles selected and selection percentage

| | Publications in 5 years | Publication selection | % publication selection |
|----------|----------------------------|--------------------------|----------------------------|
| Larynx | 2129 | 101 | 4.7 |
| J Voice | 373 | 204 | 54.7 |
| RBORL | 612 | 55 | 8.9 |
| Pró-Fono | 185 | 14 | 7.5 |

The studies were classified by objective and research design. The methodological correlation between the study objective and the study design was verified. Subsequently, this study pondered the existence of a statistical difference in methodological quality between the Brazilian publications available only in the MEDLINE® database and the international publications also available on the ISI® Web.

Election of journals included in study

The election of the journals reviewed was implemented by polling 37 speech-language pathologists and 28 otorhinolaryngologists, all specialists in voice and larynx and connected with Brazilian universities. The following question was posited: 'In your field of study specializing in the voice and larynx, what are your preferred journals for reading, keeping up-to-date and researching? List up to two national journals and two international journals.'

The responses to this question determined the four journals, with publication dates from 2000 to 2004, which were used in this study (Table 1).

Selection of articles on voice and larynx published in selected journals

This study was based only on articles concerning topics related to the larynx and/or voice (and their respective disorders), with or without clinical objectives, such as diagnosis and treatment of dysphonia (functional or organic); vocal limitations; professional use of the voice; vocal hygiene; laryngeal anatomy and physiology; testing and analysis of auditory perception and vocal quality; voice habilitation and rehabilitation; and phonosurgery, laryngeal reparatory surgeries for improvement of vocal quality and medical treatment for said improvement.

Excluded articles were about systematic larynx illnesses, speech and resonance filter, singing voice, esophageal speech, cancer, the anatomy of respiratory treatment, infections, supraglottic and isolated infraglottic changes, laryngeal papillomatosis, dysphagia, animal studies and histology studies.

Assessment and classification of said articles

The articles were analysed by two evaluators, one being a speech-language pathologist and one an otorhinolaryngologist, who individually had access to the complete articles so as to classify such. Whenever doubts arose, a third collaborator aided in the decision making.

The articles were classified according to research objective (treatment, diagnosis, risk factor, prevalence, prognosis, other [6] and primary diagnostic evaluation) and to research design (review of literature, systematic review of literature, case study, case-series study, cross-sectional study, case-control study, cohort study, historical cohort study, controlled clinical trial and other) [6].

Some articles' objectives were classified as primary diagnostic evaluation. We adopted this classification to define research that describes certain laryngeal or vocal characteristics or behaviour. Generally, an objective classified as primary diagnostic evaluation is an assessment, correlative or associative study of cases and populations. Using these studies, it is possible to identify and classify the behaviours, factors and characteristics of illnesses, body structures, people and professions, etc. Those objectives classified as other corresponded to studies that ponder questions other than those listed above or that do not include clearly defined and specified questions.

Study designs classified as other were updated articles in which the authors merely describe the method or make a suggestion concerning practical application, without submission of specific tests and results that are of practical application. This classification also included opinion articles and protocol reports.

Subsequent to the classification of all articles by both evaluators, the results were compared and analysed using two statistical tests.

Those studies encompassing a recommended study design to respond to each objective were considered adequate. Said studies correspond to the best level of evidence when used to respond to the following proposed clinical questions:

- therapeutic behaviour – randomized clinical trial or systematic review of literature;
- prevention – randomized clinical trial;
- prognosis and risk factors – cohort study or observational;
- diagnosis – accuracy study; and
- frequency – cross-sectional study.

Two statistical tests verified the evaluators' correlation in classification of the objectives and study designs:

- an accuracy test to verify the correlation percentage between the two evaluators [7]; and
- Cramer's V to calculate the degree of inter-evaluator correlation so as to verify if said degree was statistically significant. The significance level of 5% was adopted in application of the statistical tests [SPSS 13.0 (SPSS Inc., Chicago, IL)].

Subsequently, the following classification aspects were evaluated:

- frequency of the designs and objectives, in each journal and in total;

- distribution of the articles pursuant to the ISI® Web and MEDLINE® database;
- adequacy of the study design vis-à-vis the question proposed, for the ISI® Web and the MEDLINE® database; and
- chi-square statistical analysis to verify if the amount of adequate articles was the same for articles indexed for the ISI® Web as well as for the MEDLINE® database.

Results

The journals were elected by means of a vote by 65 professionals with a specialization, master's degree or doctoral degree in the field. Among said professionals, 37 were speech-language pathologists and 28 were otorhinolaryngologists.

In order of researchers' preferences, the journals *Laryngoscope*, *Revista Brasileira de Otorrinolaringologia*, *Journal of Voice* and *Revista Pró-Fono* were chosen. Of the said journals, 423 studies that met the criteria of this research were included herein.

The correlation degree between the two evaluators with respect to classification of the study objectives and of the study designs was always greater than 79% with $P < 0.001$ in the Cramer's V statistical test.

Discussions

The results demonstrated that few articles published in the specialist-selected journals incorporated an adequate methodology to respond to the clinical questions posited; that is to say, the study designs were not adequately appropriate to the respective questions and did not present reliable evidence to guide decision making in the fields of speech-language pathology and otorhinolaryngology.

The quantity of articles published with risk factors and prevention as the objectives were nearly non-existent, 17 of 374 articles in total, or 4.5% (Table 2).

Articles whose objectives were classified as primary diagnostic evaluation (101 articles), primarily in the *Journal of Voice* (74 articles) (Table 3), predominantly comprised the voice and larynx research profile that is traditionally observational and less experimental. In 1977, Moore had already demonstrated that research conducted from 1920 to 1970 was focused on better describing vocal problems, but focused little on problem resolution and therapy changes [8].

Despite an article's objective being predominantly primary diagnostic evaluation, this classification is not defined by clinical epidemiology. Rather, this type of study aids in the description of

Table 2 Articles classified by objective for each journal and percentage with respect to the total number of articles included (374)

| Purpose | Pró-Fono | RBORL | Larynx | J Voice | Total | % |
|------------------------------|----------|-------|--------|---------|-------|------|
| Primary diagnosis evaluation | 3 | 12 | 12 | 74 | 101 | 27 |
| Therapy | 6 | 12 | 40 | 37 | 95 | 25.4 |
| Other | 2 | 13 | 22 | 46 | 83 | 22.2 |
| Diagnosis | 0 | 11 | 13 | 10 | 34 | 9.1 |
| Prognosis | 0 | 2 | 11 | 12 | 25 | 6.7 |
| Frequency | 2 | 4 | 1 | 12 | 19 | 5.1 |
| Harm | 0 | 1 | 2 | 10 | 13 | 3.5 |
| Prevention | 1 | 0 | 0 | 3 | 4 | 1.1 |
| Total | 14 | 55 | 101 | 204 | 374 | 100 |

Table 3 Articles classified by design for each journal, percentage of articles by index, and percentage with respect to the quantity of articles included in this study (374)

| Study design | MEDLINE | | | ISI® | | | Total | % |
|---------------------------|----------|-------|-----------|--------|---------|--------|-------|------|
| | Pró-Fono | RBORL | % MEDLINE | Larynx | J Voice | % ISI® | | |
| Case-series | 3 | 25 | 7.5 | 37 | 61 | 26.2 | 126 | 33.7 |
| Cross-sectional | 4 | 10 | 3.7 | 10 | 59 | 18.4 | 83 | 22.2 |
| Case study | 5 | 10 | 4 | 18 | 39 | 15.2 | 72 | 19.3 |
| Other | 1 | 5 | 1.6 | 10 | 12 | 5.9 | 28 | 7.5 |
| Case-control | 0 | 3 | 0.8 | 10 | 12 | 5.9 | 28 | 7.5 |
| Historical cohort | 0 | 1 | 0.3 | 9 | 2 | 2.9 | 12 | 3.2 |
| Cohort | 0 | 0 | 0 | 2 | 9 | 2.9 | 11 | 2.9 |
| Randomized clinical trial | 0 | 0 | 0 | 3 | 3 | 1.6 | 6 | 1.6 |
| Literature review | 1 | 1 | 0.5 | 1 | 3 | 1.1 | 6 | 1.6 |
| Accuracy | 0 | 0 | 0 | 1 | 2 | 0.8 | 3 | 0.8 |
| Total | 14 | 55 | 18.4 | 101 | 204 | 81.4 | 374 | 100 |

| Study design appropriate to purpose | MEDLINE | | | | ISI® | | | |
|-------------------------------------|----------|------|-------|-----|--------|-----|---------|-----|
| | Pró-Fono | % | RBORL | % | Larynx | % | J Voice | % |
| Frequency/Cross-sectional | 2 | 14.3 | 2 | 3.6 | 0 | 0 | 9 | 4.4 |
| Prognosis/Cohort | 0 | 0 | 0 | 0 | 2 | 2 | 4 | 2 |
| Therapy/Clinical trial | 0 | 0 | 0 | 0 | 3 | 3 | 1 | 0.5 |
| Diagnosis/Accuracy | 0 | 0 | 0 | 0 | 1 | 1 | 2 | 1 |
| Prevention/Clinical trial | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 1 |
| Harm/Cohort | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0.5 |
| Total | 2 | 14.3 | 2 | 3.6 | 6 | 5.9 | 19 | 9.4 |

*The percentages contained in this table were calculated with respect to the total number of articles chosen from each journal: Pró-Fono $n = 14$; RBORL $n = 55$; Larynx $n = 101$; and J Voice $n = 204$.

laryngeal behaviour and characteristics, illnesses and populations. Studies that are primary diagnostic evaluations do not contain specific questions; they are merely conceptual and do not extrapolate from observation to point to or conclude a specific medical action or procedure.

The most common study designs were case series (33.7%), followed by cross-sectional studies (22.2%) and case studies (19.3%) (Table 3). These percentages mean that, if 25.4% of the questions concerned treatment (Table 2), the quantity of expected clinical trials should be greater from the 1.6% actually encountered in this study (Table 2).

Our results showed weak improvement as compared with the results of Reed (1980), when he affirmed that studies concerning voice efficacy are uncommon compared to that which is already known about the vocal mechanism and clinical application [9]. Ramig and Verdolini (1998), in a new compilation of publications, demonstrated that efficacy data do exist in the resolution of functional voice problems, such as vocal chord nodules, organic disorders like Parkinson's disease and psychogenic disorders [10]. That same year, Pannbacker reviewed the techniques of vocal and conclusive treatment and stated that there is a knowledge void in voice-disorder treatment [11]. Evidence for accepting or rejecting the efficacy of treatments is limited because the conditions for diagnosis are discrepant and inconsistent, and the study designs are hardly appropriate [11] as seen in Table 4.

Table 4 Total number of articles demonstrating adequate study design to study objective, by journal, by index and by percentage***Table 5** Quantity of articles demonstrating adequate and inadequate study design to study objective, by index

| | Appropriate | Non-appropriate | Total | % of appropriate articles (374) |
|---------|-------------|-----------------|-------|---------------------------------|
| ISI | 25 | 280 | 305 | 8.2 |
| MEDLINE | 4 | 65 | 69 | 5.8 |
| Total | 29 | 345 | 374 | 7.8 |

Chi-square: $P = 0.050$

Publications indexed for the ISI® Web, from the point of view of methodological quality, showed no statistical difference with respect to those indexed only for the MEDLINE® database (Table 5). Nevertheless, upon consideration that the most elaborate study designs, such as cohorts and randomized clinical trials, are all indexed for the ISI® Web and that none are indexed the MEDLINE® database, it can be said that the ISI® Web tends to include the best published research.

The chi-square calculation showed no percentage difference in quality between national and international journals, and the quantity present is insufficient to base clinical practice. The two databases, ISI® (international) and MEDLINE® (national and international), demonstrate no difference in terms of the appropriateness or adequacy of the study design vis-à-vis the question posited.

We hope Brazilian and international journals concerning voice and larynx continue to improve in terms of content. Researchers must be concerned primarily with the question that will determine which study design best responds thereto, thereby decreasing scientific, clinical, financial and educational losses. Without reliable scientific reasoning, teaching and learning process are at risk.

The practical implications of this study are relevant because health professions need scientific evidence that promote their patients' well-being and avoid unnecessary damages and inappropriate treatments. The lack of evidence encumbers decision making, places patients at risk, allows for the same disorders to be treated randomly, discredits patients by virtue of treatment as well as the administering professional and increases costs and risks.

The implications of the findings contained in this study also may allow authors, editors and professional and educational organizations to acknowledge the limits of current research and practice. Said persons hereby might consider changes in developing methodologies as well as more systematic evaluation of their articles.

Another important aspect worth mentioning concerns the importance of knowledge and the application of clinical epidemiology for graduate students, that is to say, future researchers. These students should conduct research that encompasses proper methodology and clinical evidence. Courses in clinical epidemiology and evidence-based health care must be developed at the undergraduate and graduate levels.

The development of thought based on the practice of evidence-based health care for speech-language pathologists and otorhinolaryngologists would promote the rise of a better-equipped critical mass of health care providers and avoid the waste of researchers' talents.

More appropriate studies would lead to the implementation of systematic reviews, research that would reduce uncertainty and facilitate safer conduct in health care.

Conclusions

1 Studies published in the two national journals indexed for the MEDLINE® database and the two international journals indexed for the ISI® Web demonstrate weak methodology, with inappropriate or inadequate study designs to meet their proposed objectives.

2 More research is published in international journals indexed for the ISI® Web, but there is no statistical difference between such and those indexed for the MEDLINE® database with respect to the methodology utilized to conduct said research.

3 Research with descriptive and observational objectives, without direct attempts to proffer therapeutic and diagnostic results, still predominate in the medical fields of speech-language pathology and otorhinolaryngology.

Competing interests

There are no competing interests.

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