Elaboration of a quality scale for the interpretation of spirometry in preschool children

Elaboración de una escala de calidad para la interpretación de espirometrías en preescolares

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Abstract

Introduction: Since 2007, there are international guidelines for implementation and interpretation of spirometry in preschool children. A percentage of these patients cannot obtain maneuvers that meet all eligibility criteria. The objective of this study was to develop a quality scale for interpreting these partially acceptable spirometry. Material and Method: Delphi methodology was used, which allows to reach consensus among experts analyzing a defined problem. We invited to participate pediatric pneumologists dedicated to lung function and who participated actively in scientific specialty societies in Chile. Successive rounds were conducted with questionnaires about criteria used to assess spirometry in preschool children. These criteria define the acceptability of spirometric maneuvers according to international guidelines. Proposed quality grades were “very good”, “good”, “fair” and “bad”. Results: Thirteen of the 15 invited experts accepted our invitation. In the first round 9 disagreed with the degree of “regular” quality. In the second round this was removed and 11 experts answered, 9 of them agreed with the use of this new version. The most contentious criterion was the end of expiration. Conclusion: Most experts agreed with the final scale, using “very good”, “good” and “bad” judgments. This would help to improve the performance of spirometry in children between 2 and 5 years.
Introduction

Spirometry is the most widely used test to evaluate lung function1–3. Since the 1990s, there have been several national and foreign reports about its implementation in preschool patients (2 to 5 years)4–15, and since 2007 we have international guidelines for its realization and interpretation4. In this age range, the lungs are still developing, following exponential alveolar multiplication of the first 2 to 3 years; then constant alveolar growth occurs, which is proportionally less than that of the airway, which is already definitive at birth4–16. This explains the rapid finalization of forced expiration in these children, sometimes in less than a second. Therefore, the interpretation criteria should be different from those of older children4,18. To assess the quality of spirometry, criteria of acceptability are used, which are objectively determined by observing spirometric curves, volume/time and flow/volume. Of these characteristics, those considered essential for compliance are duration of expiration greater than or equal to 0.5 s, rapid ascent in both curves (flow/volume and volume/time), visualization of maximum expiratory flow (MEF) defined curve and the smooth decrease in the flow/volume curve. The secondary acceptability criteria are the lack of retrograde extrapolation volume, which reflects a delayed onset of forced expiration, and the expiration term between 10 and 25% of the MEF4,18.

Repeatability is analyzed according to the values obtained in forced expiratory volumes, considering in this age group a variation of no more than 10% in the 2 best values of forced vital capacity (FVC) and forced expiratory volume in the first second and/or in the 0.5 s (FEV1 and FEV0.5, respectively)2–3,18.

In a national study, Donaire et al.12 observed compliance with all acceptability criteria in 50% of spirometry results. In these, compliance with a single criterion failed in 25% of the total, this being the “end-expiration” in all cases (unpublished data).

The literature does not refer to the interpretation of spirometry results that do not meet all the criteria of acceptability proposed by international recommendations1. Therefore, the need of creating a form of valuation that allows to optimize the examination performance originated, avoiding new appointments for the patient and contributing in a timely manner to the therapeutic decision making. Since there is no evidence, and since this situation is a complex problem, it cannot be determined by a single professional due to the risk of biases and imperfections. For this reason, a valid option to solve this problem is to obtain an agreement of experts, based on their experience and judgment on the subject.

The creation of a measurement instrument requires criteria or domains that represent what it needs to be measured, in this case spirometry acceptability criteria. This has been called validity. A first component of validity is content, which is purposed to define and represent, initially through expert judgment, the criteria that would account for what they want to measure19.

The objective of this study was to create a quality scale to interpret spirometry on pre-school children, who do not meet all the acceptability criteria proposed by the international guidelines.

Material and Method

Following international recommendations for the interpretation of spirometry in pre-school children, a quality scale was elaborated based on the acceptability criteria of volume/time and flow/volume curves. Before being sent to the experts, the scale was applied by the coordinating group in their respective places of work, being modified in 2 opportunities, finally creating the scale (fig. 1).

The study was carried out with Delphi methodology. This is a prospective technique that seeks the consensus of a group of experts analyzing a problem defined by using previous research results and own experience, instead of leaving the decision to a single professional, when there is no objective information about the theme. The development is carried out in successive stages or rounds supervised by a coordinating group until a definitive agreement is reached20–25.

The stages of this process were as follows:

1. Definition of the problem: there is no agreement for the interpretations of spirometry that do not meet all the requirements of acceptability in preschool children; no history is found in medical literature.
2. Establishment of the coordinating group (FG, CU, HB, SC), whose role was to create the content of the scale, create the questionnaires, select the group of experts, favor their participation and analyze the answers.
3. Expert group: A non-randomized sample was used for the purpose of choosing pediatricians specializing in respiratory diseases dedicated to pulmonary function. Those who are an active part of the scientific societies of the specialty in Chile were invited to participate.
4. Procedure for obtaining answers: the content of the quality scale was analyzed using a survey with a Likert scale using 2 categories (agreement-disagreement), in addition to the possibility of making a comment (open response) for each of the items raised or the introduction of any new items. This procedure was performed in 3 rounds:
4.a. First round: Once the first version of the scale and its survey were made, they were sent by email or in person to each of the experts, giving them a set deadline to respond. Together with these, a document with a brief introduction to the subject of research, explanation of its purpose, method used and a brief description of its foundations, the stage of the research process and the instructions for responding to the survey were presented. In addition, a copy of the international guide for the interpretation of spirometry in preschool children and graphic examples of spirometry for each of the quality grades were sent. After the deadline, and with all the data collected, the coordinating group proceeded to analyze the results, reaching a consensus that resulted in the second version of the quality scale.
4.b. Second round: the second version of the scale was sent along with a survey to each of the experts, requesting a response on the degree of agreement and comments. In this opportunity a virtual platform (SurveyMonkey) was used, using the same way as for the collection of the results. Again, the coordinating group performs an analysis of the results, with which a consensus is reached creating the third version of the scale.

4.c. Third round: Final results are sent for approval by the experts. The coordinating group proceeds to the final report.

The analysis of each round consisted of reviewing the proportion of experts who agreed or disagreed with each item. In the following round the consensus version is shown and proceeded in the same way, until an instrument with a greater proportion of agreement among experts is reached. This project was approved by the Ethics Committee of the Medical Research Center of the Faculty of Medicine of the Pontificia Universidad Católica de Chile (Waiver of informed consent, Project number: 14-053).

The project did not require funding.

Results

15 experts from Santiago and provinces were invited, 13 of whom agreed to participate. The 2 who refused to participate reported that they had not performed spirometry in preschoolers. Seven belonged to private institutions and 6 to both public and private institutions; 10 were women. The age range was between 34 and 66 years, with a median of 50 years. In the first round all responded, and in the second round 11 answered.

In figure 2, after the first round, the degree of agreement/disagreement is shown with each of the acceptability criteria that be present for the interpretation of spirometry. With regard to the “fair quality” classification, 52% felt that it should not be used. For the classification of spirometry as “poor quality,” 100% of the respondents agreed with this denomination if there was failure in 3 or more of the presented variables. Table 1 summarizes the comments about this first version of the quality scale. None of the respondents recommend changing the defining criteria for each degree of quality.

The coordinating group analyzed the above, making the recommended changes, that is, eliminating the qualification of “regular quality”. This was the second version of the scale, with only 3 grades of quality, which was sent back to the group of experts. Nine of the 11 respondents in the second round agreed on the use of this new version, and their final comments were: “I find that it is useful and allows criteria to be unified”, and “it is simple, clear, easy to use, and very useful and allows to unify criteria.” The 2 experts who disagreed did not accept that the expiration term was greater than 10% of the MEF.

Figure 2. .
**Tabla 1. Principales comentarios de la primera ronda**

De acuerdo con los criterios internacionales, pero exigiría un tiempo espiratorio > 1 s en la “buena” y en la “muy buena” (4 encuestados)

El volumen de extrapolación retrógrada no tiene importancia si se cumple el resto (2 encuestados)

El FEM definido no puede faltar idealmente, pero si no lo logra perfec-
to, sería el segundo componente que podría ser menos rígido, pero es analizable caso a caso ya que puede llevar a errores diagnósticos si no se analiza bien (2 encuestados)

Se recomienda que la escala cuente solo con 3 grados de calidad: “muy buena”, “buena” y “mala o no interpretable” (5 personas)

FEM: flujo espiratorio máximo.

**Discussion**

Spirometry on pre-school children is a reality in our country\(^{12-15}\), with a considerable number of specialists dedicated to pediatric lung function. It is known that a percentage of patients do not achieve completely acceptable efforts\(^{26-28}\); however, obtained spirometric curves evidence ventilatory normality. It is considered useful therefore, to obtain some tool to interpret spirometrics of lower quality. Since there is no evidence to solve this issue, we use the Delphi method, whose objective is to reach consensus in an area of uncertainty and lack of evidence\(^{20,25}\), obtaining finally a spirometry quality scale for the assessment of this age group.

Among the collective national pulmonary function pediatricians who met the criteria described for their selection in this study, 86% of them participated in this study, which grants a greater validity to the content of the scale, since the level of agreement was considerable: 9 of the 13 experts who initiated the process agreed on the scale in the second round. Considering the result following the whole process, 9 of 11 specialists were in agreement.

The Delphi method is characterized by being an iterative process (successive rounds), anonymous and with feedback, allowing each expert to reconsider their opinion\(^{21}\). The responses of the participants are not disclosed, ensuring control over leadership influence, which was accomplished through our work. Through the analysis of the conducting group, common information flow is obtained among the experts, a common language is developed, and information is made available to the different participants, which before the process was unknown to some\(^{24}\). Another advantage offered by this method is that, when performed via e-mail or virtual platform, it overcomes geographic gaps and does not require gathering all the participants together, allowing a faster response. We managed to gather opinions of experts from different health centers in the country, both public and private, in Santiago and regions, with a loss ratio similar to that described\(^{23}\). However, the fact of not having face-to-face meetings with the experts made it difficult for the coordinating group to give greater emphasis to the most discussed criteria.

Among the spirometric interpretation variables described as fundamental to be fulfilled according to the international guidelines\(^3\), there was no discrepancy among the experts for the ascending form of the flow/volume curve, the defined MEF, or the smooth descent of the flow/volume curve. The retrograde extrapolation variable was considered by only half of the specialists. In international guidelines, this criterion does not correspond to the fundamental group, and it is recommended not to eliminate operations with retrograde extrapolation volume that exceed the limits of 80 ml or 12.5% of FVC\(^3\).

With respect to duration of expiration, 4 of the 13 experts did not agree to require that, in order for a spirometry in a preschool to be rated as "very good quality", an expiratory time of 0.5 s is enough. Similarly, for “good” quality 2 out of 13 agreed, and for “fair” quality 3 out of 13 agreed. We have no explanation for this, as it does not match what the international guidelines propose\(^3,7\). As explained earlier, due to the disproportion between pulmonary volume and airway caliber, pre-school children are able to express their FVC in a shorter time than older children, considering an expiratory time of 0.5 s to be enough. Currently, all investigations involving pre-school children report satisfactory results with expiratory times of less than one second, such as FEV 0.5 and FEV 0.75\(^3,7,9\). The condition is that the flow/volume curve must be “good quality”\(^3\).

The last criterion that caused controversy was the abrupt end of expiration. International guidelines recommend that if an end of expiration is not achieved at a flow below 10% of the PEF, the operation should not be discarded, allowing the interpretation of expiratory volumes according to time (FEV0.5 or FEV0.75), but not FVC or forced expiratory flows\(^3\). This abrupt endpoint should be reported and, in general, be based on what has been previously described with respect to lung development. In some children it could be caused by glottic closure, abrupt expiratory cessation or because the child covers the tube with the tongue, as seen in older children. In these cases, the technician’s experience is essential to identify the cause. Some authors\(^4,28,29\) use the value of 25% of the PEF to delimit the end of expiration, since the value of 10% was arbitrarily designated and has not yet been validated\(^28\). At the stage of quality scale elaboration, the coordinating group decided to adopt 25%, since it was observed that using 10% does not make possible to interpret a large number of spirometric results.
It was not considered, in order to define the quality of spirometry, the criterion of repeatability of FVC values and FEV0.5, FEV0.75 or FEV1, which should be a maximum of 10% among the 2 best values of each of these variables. The guidelines to interpret spirometry in preschoolers allow to choose in isolation the operation that shows the highest values of expiratory volumes, although not repeatable, that comply with the acceptability characteristics. Initially, repeatability was included in the proposed classification; however, after a trial-run was made, it was necessary to increase the number of degrees of quality if that was included, complicating the analysis requested from the experts.

One of the strengths of this study is that it addresses a problem not yet defined, using a standardized methodology. In addition, this new scale will allow quality control of the exams and will lead to obtaining reliable spirometric curves to interpret. Otherwise, the practitioner interpreting the test may rate the quality of the test by guiding the treating physician about the applicability of such spirometry.

This scale aims to contribute to the performance of spirometry with children between 2 and 5 years. Compared to the study of Donaire et al., the yield increases by 25% when applying this instrument.

Conclusion

The method used demonstrated that it was possible to achieve consensus on an uncertain and disproven issue by combining the knowledge and skills of the expert group. Most of the experts agreed with the criteria chosen to rate spirometry according to their quality as "very good," "good," or "bad." Because more than half of them did not agree to use the "fair" rating, it was eliminated. Using this new quality scale helps to improve the performance of spirometry performed in children between 2 and 5 years. We present the need to complete its validation process in order to apply it in laboratories of pulmonary function and to join criteria among specialists.

Ethical Responsibilities

Protection of people and animals: The authors state that no experiments have been performed on humans or animals for this research.

Confidentiality of data: The authors state that no patient data appears in this article.

Privacy rights and informed consent: The authors state that no patient data appears in this article.

Conflict of Interests

The authors declare that they have no conflict of interest.

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