Sweat conductivity has optimal repeatability in newborns and young infants

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To the Editor,

Sweat conductivity (SC) is a well-established screening test for Cystic Fibrosis (CF).[1,2] It is semi-automated, fast, doesn't require skilled technicians or specialized personnel, and needs a small amount of sweat. Moreover, one response to the demanding and labour-intensive requirement for robust quality sweat testing has been the testing of sweat samples by electrical conductivity.[3]

As every laboratory method, SC is subject to error. Then, it should be assessed and tested to ensure that it produces results which make it reliable and suitable for the intended purpose, i.e., its role as screening method. Repeatability is one of these vital requirements.

The International Organization for Standardization defines repeatability as the nearest agreement between independent test results performed in identical conditions in a short period of time, i.e., same test items and steps, same equipment, same technician, same laboratory.[4]

Although SC is adopted worldwide there is no study evaluating specifically that requirement in any age group, including newborns and young infants. Therefore, the present study aimed to assess the correlation between two concomitant SC assays**.**

We prospectively and consecutively recruited clinically stable infants younger than 3 months. They had two previous positive immunoreactive trypsin results (IRT), and then, two concomitant SC assays, performed by the same technician in the same facility. IRT and SC were carried out in the single accredited Reference Center for Newborn Screening and Genetic Diagnosis, located in the city of Belo Horizonte, State of Minas Gerais, Brazil.

Sweat samples were obtaining from each forearm through the Wescor Macroduct system[?] and then analyzed through a SC analyzer (Sweat-Chek analyzer[?], model 3120, Wescor Inc., USA). All steps were performed according to the manufacturer's recommendations, and described elsewhere.[1,2]

Apart from descriptive statistics, to assess the relationship between the two SC assays we used Spearman's rank correlation coefficient. SPSS software, version 18.0 (SPSS Inc., Chicago, Illinois) was used for statistical analyses. The research protocol was approved by the Research Ethics Committee of Federal University of Minas Gerais, under number CAAE 21958014.1.0000.5149.

A total of 322 young infants were recruited. Most of them (89%) were from smaller towns within the same State, and 11% lived in Belo Horizonte, the State capital. There was a slightly predominance of males (54%), and the majority (59%) were younger than 60 days, being 15.2% of them aged up to 30 days of life. Mean and median age was 52 and 46 days (range, 19-89 days), respectively.

A sufficient amount of sweat was obtained from all participants. Means and medians for the first and second SC values were 37.0 mmol/L, and 34.3 mmol/L (range, 29.0-39.6 mmol/L), and 38.0 mmol/L and 35.3 mmol/L (range 30.0-40.7), respectively.

Figure 1 displays the Spearman's correlation scatter plot for the two SC results.

Insert Figure 1

There were two main results distribution, i.e., lower and higher than 60mmol/L and 80mmol/L, respectively, with no intermediate values. A strong, statistically significant correlation ($r_s = 0.83$; $P < .05$) between the two concomitant assays was found; moreover, the difference between the 95% CI lower and upper limits (0.08), denotes high accuracy of our results.

Although SC is used worldwide, to the best of our knowledge there is no previous work that had been attempted to assess its repeatability, regardless the age group. Therefore, the unavailability of previous studies hinders comparisons with our results.

In conclusion, the strong, statistically significant repeatability found in the present study, testify to the clinical usefulness of SC, adds original evidence, and reinforces its role as a reliable screening test for CF.

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CONFLICT OF INTERESTS

The funding organization(s) played no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the report for publication.

AUTHOR CONTRIBUTIONS

RMB contributed to manuscript conception, writing, revision and editing. CGA contributed to manuscript conception, writing, editing and to critical revision of the manuscript. OGS contributed to data collection, interpretation and analysis. DN supervised and/or performed SC assays. JVAJ and FHP contributed to data collection, analysis, validation, and interpretation, and writing of the manuscript. PC conceived the study, and the study design; investigation, methodology, funding acquisition, project administration, resources, validation; manuscript conception, writing, editing and to critical revision of the manuscript.

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