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Treatment of acute asthma in developing countries

Dear Editor,

We fully appreciate the study conducted by Vilarinho et al.[1] published in *Jornal de Pediatria*, as we are in the process of implementing the referred form of asthma treatment in a public emergency room, where more than 33,000 children are treated every year. In this case, acute asthma accounts for 13% of regular visits to a pediatrician.[2]

Metered-dose inhalers with or without spacers have been extensively studied in the pediatric population, being a consensus-based approach recommended for the treatment of acute and/or persistent asthma.[3] However, we do not know any public or private emergency room in Curitiba that has established it as a routine practice. After Zar et al.[4] encouraged the use of homemade spacers (using plastic soft drink bottles) to replace commercially produced ones, obtaining a reduction in costs and a similar efficiency, other studies were conducted showing their benefits. One of these studies was carried out in Juiz de Fora, Brazil.[5]

This is of paramount importance for developing countries, where treatment alternatives that could reduce costs and be efficient have been sought. With the aim of getting familiar with and verifying how these devices would work in the population in their region, Vilarinho et al. conducted a well-intended study, but some ethical and methodological aspects should be reconsidered:

1) Resolution 196/96 of the National Health Council (Brazilian organization that prescribes the standards for research involving human subjects) does not allow the use of an exclusive placebo group in this situation, due to the nonmaleficence principle. However, if the study had been double blind and placebo-controlled, the reliability of results could have been improved.[6]
2) The lack of free and clear consent signed by parents and/or legal guardians may result in legal complications in the future, especially because children aged less than 18 are involved. The verbal authorization and the questions about whether the device was well accepted or not were always targeted at parents. Were the children, at least those who are able to answer such question, interviewed?
3) The careful preparation of a research study reduces the possibility of biased results. For that reason, a pilot study is necessary for sample size estimation so as to provide an appropriate statistical power.[7] Today, we seek evidence-based medicine,[8] and not only an approach that mirrors "real life", as considered by the author.
4) The groups were homogeneous in relation to the severity of asthma attacks. Why was oxygen supplied only to the NEB group? Could the MDIS group obtain a better performance with oxygen inhalation after salbutamol administration? Would the treatment costs of the NEB group be overestimated due to the use of oxygen?
5) The Wood-Downes score for the classification of the severity of dyspnea and wheezing crisis ranges from 0 to 2 for each evaluated parameter, and was validated by Paes et al.[9] Is the adaptation of this score in the study of practical value?

We should continuously attempt to find an efficient and low-cost alternative for the treatment of acute asthma, but we should be careful with the implementation of new ideas, by using appropriate scientific methodology before we disseminate them. Otherwise, we run the risk of turning these brilliant discoveries into a "tupiniquim" (rudimentary or amateurish) way of medicating, since we may be faced with ethical and civil lawsuits both resulting from research and "real life" situations.

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Authors' reply

Dear Editor,

The treatment of children with acute and chronic asthma in Brazilian public health services is still inadequate. There is ample evidence that inhalation therapy is the best option since it is effective and has fewer side effects.[1] Ethical solutions must be sought so as to facilitate treatment, especially regarding the use of metered-dose inhalers with a spacer, which allow more medicine to reach the lungs.

The study published in *Jornal de Pediatria* "Metered-dose inhalers with home-made spacers versus nebulizers to treat moderate wheezing attacks in children" originated from the necessity to validate a current practice at the Teaching Hospital of Universidade Federal da Bahia (UFBa), which employs homemade spacers with metered-dose inhalers for the treatment of asthmatic children, especially younger ones or those who have difficulty using or adapting to nebulizers. The necessity to replace nebulizers with metered-dose inhalers arose as an attempt to reduce hospital costs with oxygen. Moreover, the operational advantages are well known, as reported in studies with plastic coffee cups and different-sized and different-shaped inhalers (valved and non-valved, sealed or unsealed).[2-5] Because of its importance, this issue became the object of study of a dissertation, written by one of the authors (LCS Vilarinho) and supervised by another author (LS Freitas-Souza), where methodology and ethical aspects were exhaustively discussed. A pilot study was carried out, not to calculate the sample size (pilot studies are not intended to do so), but to check internal validity. Since it was not possible to calculate the sample size previously, we opted for a convenience sample, which indicates that the study is terminated when we find resource limitations of any kind. Therefore, the calculation of statistical power was only made later on. However, we could not achieve a statistical power of 80% due to the sample size. To achieve that, the sample should have been larger.

It is not within the scope of our study to comment on the use of placebo, since we are not comparing drugs but inhaler devices instead. Moreover, this is completely unethical according to the resolution of the National Health Council. How could we refuse to treat a patient if there is a provably efficient treatment and if there is life risk involved?

We required verbal informed consent so that we may use the collected data in scientific studies, once the therapeutic procedures, i.e. nebulization or use of metered-dose inhalers with homemade spacer, have been a routine practice in our emergency room since 1996.

The term "real life" is related to the inclusion of all ages from 0 to 12 years, which represent the ages of patients treated in our emergency room. If we had restricted age, we would be able to use our results only in special cases. This is deliberately also part of the methodology. Our choice results in possible confounding variables (e.g.: inclusion of nonasthmatic wheezing infants who could be weakly responsive to the use of bronchodilators), but it allows us to evaluate the outcome of both treatments as a whole, and to answer the following question: Is it advantageous to use metered-dose inhalers with a metered-dose spacer in children of any age in the emergency room?

Oxygen was supplied to the NEB (nebulizer) group only to produce aerosol spray in the jet nebulizer. Compressed air could have been used instead. But compressed air was not available at Centro Pediátrico Hosannah de Oliveira - CPPHO (Hosannah de Oliveira Pediatric Center): nebulizations with oxygen were used. By observing the values of pulse oximetry (mean, minimum and maximum values, and median) in Table 3 in the referred article, we may conclude that, although oxygen was not used, the MDIS (metered-dose inhaler with spacer) group had a hemoglobin saturation equal to or greater than that obtained in the NEB group and, according to the baseline values (T0), none of the groups would require the use of oxygen.

Nebulization costs are higher because of the oxygen necessary to produce the aerosol spray. Installation costs and the use of compressed air are much cheaper, about one third of the expenditure on oxygen, but they were impracticable in our setting at the moment of the study. Portable compressed air devices do not produce appropriate aerosol spray: particles are large and diameter varies considerably; therefore, they should not be used.

The Wood-Downes clinical asthma score is based on the results of blood gas analysis and, therefore, it should not be used at the beginning of treatment because blood gas analysis is not performed at this moment (not necessary), only oximetry is (whenever possible). This is the reason

why we drew up the table used in the referred article, including clinical parameters that indicate lung function involvement (some of which can be found on Wood and Downes score) and oximetry, which is a validated parameter for the study of asthma severity.[6]

Our study was developed based on appropriate scientific methodology, as specified in "Materials and Methods". As described in the "Discussion", the study is preliminary since we use a convenience sample, without previous sample calculation, due to the paucity of studies in the literature that use a similar methodology, which could be used as a basis for sample size calculation; now, our study can provide other studies with a sound basis for this calculation should there be any interest in extending this line of research.

We express our strong disapproval of the derogatory use of the term "tupiniquim" (meaning rudimentary or amateurish). In our viewpoint, we Brazilians have to leave behind the cultural and scientific colonialism in which we live and seek our own identity, develop our own knowledge-producing capacity based on our necessities, and have the courage to express it.

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Smoking in pregnancy: a bigger problem than you think

Smoking compromises female pre-conception reproductive function, pregnancy outcome and lactation.[1] Since pregnant women usually are in close contact with health professionals (prenatal care), antismoking campaigns are frequently successful in this period. However, for these efforts to succeed the following considerations should be emphasized.

First, while the illicit drug use in pregnancy has received significant attention over the past two decades far too little attention has been given to the consequences of the use of "social drugs" such as tobacco, ethanol and caffeine, which are by far the most commonly used substances in pregnancy.

Second, while the deleterious effects of cocaine, amphetamines, and opioids on the mother and the fetus are more pronounced and easier to detect, the addiction to tobacco, ethanol and caffeine is usually subtle and more difficult to diagnose.[2] As a result recreational use of tobacco in pregnancy may continue undetected, significantly effecting pregnancy outcome and lactation.

Third, approximately 80% of women who smoke before pregnancy continue to smoke when pregnant.[2] Low cigarette consumption prior to pregnancy is the best predictor for smoking cessation in pregnancy.

Fourth, the majority of patients with a history of drug use in pregnancy (including tobacco) deny it when interviewed by primary care physicians, obstetricians and/or neonatologists.[3]

Fifth, risk factors suggesting tobacco use in pregnancy include lack of prenatal care, respiratory complications and history of premature labor.

A high index of suspicion for tobacco (as well as other social and illicit drug) use in pregnancy, combined with non-judgmental questioning of every parturient is therefore necessary.

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