

PostScript

LETTERS TO THE EDITOR

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Usefulness of GOLD classification of COPD severity

In 2001 the US National Heart, Lung and Blood Institute (NHLBI) and the World Health Organization announced guidelines for the diagnosis, management, and treatment of COPD (Global Initiative for Chronic Obstructive Lung Disease, GOLD).¹ One key aspect of these guidelines is that COPD is classified by severity into five stages which constitute the basis of treatment recommendations. However, to date there has been little evidence for the usefulness of these severity stages.

We retrospectively reviewed 1000 patients with COPD diagnosed clinically in 2001; 500 patients originated from a pulmonary rehabilitation hospital. Patients' symptoms (based on a standardised interview), findings of a standardised lung examination, lung function

data, and chest radiographic findings are routinely documented in a database. The inclusion criteria were symptoms of COPD (chronic cough with chronic sputum production for more than 2 years) and radiographic findings of COPD (hyperinflation, diaphragmatic flattening). Patients with a history of asthma (variability of spirometric parameters, improvement in forced expiratory volume in 1 second (FEV₁) of >20% after inhalation of β_2 agonists, symptoms predominantly at night, seasonal allergies, allergic rhinitis, or eczema) were excluded from the study, as were those in whom FEV₁ and forced vital capacity (FVC) differed by more than 5% according to the American Thoracic Society (ATS) guidelines² and patients with an abnormal chest radiograph or chronic cough caused by a disease other than COPD.

FEV₁ and FEV₁/FVC were determined three times. The predicted values for FEV₁ were taken from the European Respiratory Society (ERS) guidelines.³ The individual values of FEV₁ and FEV₁/FVC for all patients are shown in fig 1. Almost 14% of patients clinically diagnosed as having COPD could not be classified because they had an FEV₁/FVC ratio of >70%, despite having a reduced FEV₁ (<80% predicted). This combination is not represented in the GOLD classification. Less than 5% of all patients were classified as GOLD stage I.

The finding that the GOLD classification missed an important subgroup of patients with mild COPD challenges any proposed advantage of this classification scheme over existing guidelines from the ATS⁴ and ERS.⁵ Only six patients not classified as having COPD by GOLD were missed using the ATS criteria (stage I: FEV₁ \geq 50%) and ERS criteria (mild: FEV₁ \leq 70% and FEV₁/FVC >88% for men and >89% for women). Obviously, any arbitrary classification of a continuous variable such as FEV₁ and FEV₁/FVC results in a borderline group of patients. The GOLD classification, however, provides no guidance

as to the further diagnosis of the unclassified subgroup (fig 1). Our results also show that stage I disease (FEV₁/FVC <70% and FEV₁ >80% predicted) was very rare, constituting only 4-5% of the patients. This indicates that the distribution of the stages, especially stage I, is inhomogeneous.

Despite its retrospective design, this study was strengthened by the fact that lung function data, chest radiographic findings, and the results of a standard clinical examination were available for all patients. It therefore offers the chance to investigate the clinical impact of the GOLD classification, especially in patients with mild COPD.

Our study therefore suggests that GOLD criteria miss an important subgroup of patients with clinically diagnosed COPD, which reduces its usefulness as a clinical tool.

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Sahaja yoga in asthma

Since the publication of our paper on Sahaja yoga in the management of moderate to severe asthma¹ we have received a large number of enquiries. One issue that has been raised about the technique used in the study warrants clarification and further acknowledgement.

The Sahaja yoga meditation technique used in the study was *not* developed by the authors. The technique was taught to subjects in the intervention group by experienced Sahaja yoga practitioners free of charge. The technique itself was developed by yoga expert H H Shri Mataji Nirmala Devi and she permitted the investigators to conduct the study on the following reasonable conditions: (1) that no part of the technique be misrepresented, misappropriated or commercialised by the investigators; (2) that the founder and practitioners of the process be appropriately

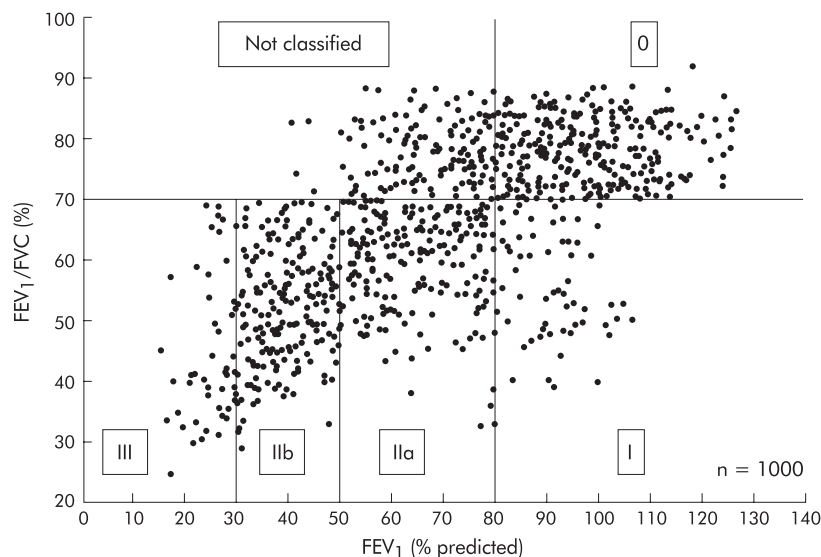


Figure 1 Plot of % predicted forced expiratory volume in 1 second (FEV₁) against the ratio of FEV₁ to forced vital capacity (FVC) (%) of the total population (n=1000).

acknowledged as the true source and custodians of the technique and its associated knowledge; and (3) that it be made clear that the Sahaja yoga technique is, as a matter of policy and philosophical conviction, always made available free of charge.

The authors sincerely regret any misunderstanding that may have led readers or members of the public to believe otherwise. They sincerely and gratefully acknowledge the important and crucial role played by HH Shri Mataji Nirmala Devi and the Sahaja yoga practitioners of Australia in the execution of this study, and sincerely regret not having made more appropriate acknowledgements in the original article.

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Homeopathy in childhood asthma

We read with interest the article by White *et al* on the use of homeopathy as an adjunct in the treatment of childhood asthma.¹ We also obtained negative findings in an open study in which we assessed the effects of homeopathy on spirometry and exhaled nitric oxide (eNO) in children with stable asthma.

Twelve asthmatic children (4 boys, median age 13.5 years, range 7–18) who satisfied the following inclusion criteria were recruited: (1) stable asthma with no clinical indication for change in treatment, on any dose of inhaled corticosteroid and any other asthma medications; (2) raised eNO level at the start of the study despite clinical stability; (3) identifiable sensitivity to house dust mite (HDM, n=3) or cat and HDM (n=9) by history and skin prick test (SPT); (4) no hospital admission or emergency department attendance for asthma in the previous 3 months; (5) no history of consumption of oral corticosteroid in the previous 3 months; (6) no homeopathic treatment within the previous 6 months, allergen desensitisation within the previous year, or HDM avoidance measures or removal of household pet to which the subject had a positive SPT in the previous 3 months.

At baseline all recruited patients underwent SPT if this had not been done within the previous 2 years, eNO measurement (NIOX, Aerocrine, Sweden), and spirometric testing (Vitalograph, Buckingham, UK) measuring forced expiratory volume in 1 second (FEV₁). The mean of three best efforts was recorded and the result was expressed as percentage predicted. The homeopathic remedy was prescribed according to the child's SPT result. This was a preparation of HDM or cat dander (or both, if appropriate) in the form of two lactose globules. The preparation was made up according to the principles laid out in the British Homeopathic Pharmacopoeia. The patients were told to take the globules daily for the next 4 weeks while continuing with the same conventional asthma treatment. A diary was given to each child to encourage compliance and to document any breakthrough symptoms or side effects from the remedy during the study period. The subjects were told to return for eNO measurement and spirometric assessment after 4 weeks (visit 1)

on the homeopathic remedy, and to return again 4 weeks later (visit 2) to assess the response after stopping the remedy. The spirometric test results of one patient from the first and second visits were missing.

No side effects were reported and all subjects were compliant with the homeopathic remedy. Using the Wilcoxon signed ranks test, there was no significant difference at baseline and at visits 1 and 2 in FEV₁ (86% (interquartile range (IQR) 81.1–93.3) v 89% (85.0–100.0) v 85% (74.0–89.0), respectively) and eNO (54 ppb (IQR 36.2–99.6) v 68 ppb (37.0–87.0) v 76 ppb (43.6–131.4), respectively). This could be because of the small sample size or because the homeopathic remedy genuinely did not have any anti-inflammatory effect.

This study provides important baseline data for the calculation of the sample size needed to carry out a randomised, placebo controlled, double blind study. A sample size of 65 subjects per treatment arm would have 80% power to detect a difference of 10% in mean FEV₁, assuming a standard deviation of difference of 28.86, using a paired *t* test with a two sided significance level of 0.05.

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Homeopathy deserves to be scientifically appraised by good quality studies and the results published without bias which could distort future meta-analyses. The study on childhood asthma by White *et al*¹ published recently in *Thorax* has critical flaws which seriously undermine its conclusion. The main weaknesses of the study, which were mentioned by the authors but not given due attention, were the limitations of the primary outcome measure and the mildness of the children's asthma. However, there is also concealed selection and measurement bias which could have been prevented when planning the trial.

Available guidelines for the diagnosis of asthma were not properly used for inclusion of patients, leaving room for doubt as to whether or not the included patients had asthma. Classification of asthma severity could be established at entry by using published international paediatric asthma consensus or guidelines.² Better physiological measures could have been used—peak expiratory flow results are less reliable than forced expiratory volume in 1 second, which is the most reproducible pulmonary function parameter.³ All patients were using β adrenergic inhalers and more than two thirds had been prescribed inhaled steroids at baseline and were well controlled; at least 50% of patients in the homeopathic group had had no asthma event in the previous 12 months, suggesting a design bias against homeopathy (ceiling effect). Sample size was calculated without a pilot study and did not allow for the fact that comparisons of the impact of asthma

treatments on quality of life are likely to involve relatively small effect sizes even when one treatment is clearly superior.⁴

My paper on the safety of homeopathy⁵ is misquoted; it does not in any way imply that the rate of exacerbations is a "hallmark of successful treatment". Instead, I stated that "one needs to consider the way practitioners are informing patients of the possibility of such aggravations after using homeopathic medicines, thus creating some expectations that will fulfil what was said in the consultation".

Finally, I cannot agree with the statement that the trial was designed with the input of experienced homeopathic practitioners for optimal conditions: individualised prescription of homeopathic medicines needs a good medical understanding of asthma to discriminate between disease-specific and patient-specific or peculiar symptoms. Treatment was by non-medically trained homeopaths without proper medical supervision, and this has implications on the selection of medicines. Medical doctors prescribing homeopathic medicines know what the patient has in terms of conventional diagnosis and can distinguish features typical of the disease from those specific to the individual patient. This was not adequately considered by the authors in planning the study.

Taken together, these biases seriously undermine the validity of the claimed results. Such shortcomings should be eliminated from future trials of homeopathy for asthma published by respected journals such as *Thorax*.

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The efficacy and clinical effectiveness of homeopathy engenders considerable debate; it is therefore essential that clinical trials are accurately interpreted and reported. The recent publication by White *et al*¹ has highlighted this issue.

The study—which assessed classical homeopathy as an adjunctive treatment for childhood asthma—concluded that, based on the primary outcome (the active quality of living subscale of the Childhood Asthma Questionnaire), classical homeopathy was not superior to placebo. We disagree with this conclusion. The scale used to assess the primary outcome was inappropriate; it does not distinguish between asthmatics and non-asthmatics² and