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Position paper

*Statement on self-monitoring of peak expiratory flow in the investigation of occupational asthma

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Occupational asthma is a disease characterized by variable flow limitation and/or airway hyperresponsiveness due to causes and conditions attributable to a particular occupational environment and not to stimuli encountered outside the workplace (1). The investigation of occupational asthma requires a stepwise approach, but the crucial point is to confirm the cause-effect relationship between occupational exposure and asthma (2, 3). Specific inhalation challenge tests (4) either in the laboratory or in the workplace are used to confirm this relationship between the workplace and the symptoms, to relate the symptoms to a specific agent, and to reproduce the temporal relationship between exposure and the onset of symptoms.

The use of serial peak expiratory flow (PEF) monitoring has also been advocated in the diagnosis of occupational asthma as an objective confirmation of the relationship between the workplace and symptoms.

PEF monitoring has been used in the investigation of asthma since 1969 (6). However, Burge et al. were the first, in 1979, to propose this method for the assessment of occupational asthma (7, 8). Because of its simplicity, the popularity of the method has increased greatly in recent years, but it soon became clear that, despite its simplicity, several aspects, both methodological and conceptual, had to be carefully defined. Much work has been done by several researchers to clarify the different aspects of PEF monitoring in the investigation of occupational asthma (9–16) and, although several points have still to be clarified, there are enough data to allow a first summing-up of the results.

This document is intended for use by physicians dealing with occupational asthma. The main points addressed are as follows:

1.0. Definition of PEF and instruments

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2.0. Means of PEF self-monitoring
3.0. Expression and interpretation of data
4.0. Advantages of PEF self-monitoring
5.0. Limitations
6.0. Recommendations
7.0. Conclusions

1.0. Definition of PEF and instruments

PEF is the maximum flow achieved during a forced expiration starting from the level of maximum lung inflation. Like other indices derived from the forced expiratory manoeuvre, it is usually considered to be an indirect index of airway calibre. On the flow-volume curve, PEF is measured on the first effort-dependent portion of the forced expiratory manoeuvre, unlike other indices which can be partially or primarily determined by the dynamic effort-independent properties of the airways. Thus, PEF, FEV_1 and maximal expiratory flow are not interchangeable indices of airway calibre and the sensitivity of these parameters in detecting airway obstruction is different, with PEF generally having a low sensitivity (16, 17).

Various types of instruments can be used to measure PEF, including pneumotachometers, spirometers, turbines, and anemometers. For PEF self-monitoring, the most suitable are portable peak-flow meters which measure only PEF, indirectly deriving it from pressure generated in a forced expiration. These instruments are mass-produced and relatively inexpensive. They should satisfy recently detailed criteria (17, 18). In particular, all peak-flow meters should be carefully calibrated using a computer-driven syringe (17). There should be a linear relationship between flow delivered to and that recorded by the instrument. Peak-flow meters should be capable of giving values in the range of 60–800 l min, except those models designed for the low range of 30–350 l min. There are concerns about the accuracy of the instruments (19, 20). Although the meters give reasonably accurate readings at low flows, they may overread by about 70 l min in the middle of the range and underread by about 50 l min in the high range. Thus, currently available instruments may distort flow rates.

Recently, new portable instruments derived from standard peak-flow meters have been developed. These instruments are able to assess PEF and store timings and values on a computer chip. Their ability to estimate compliance and the accuracy of the results balance the disadvantage of their higher cost compared to standard peak-flow meters.

All instruments come with clear instructions about care, cleaning, and disinfection of the instrument and the detachable mouthpiece.

2.0. Means of PEF self-monitoring

2.1. Instructions for the patient

Each patient should be given detailed written and verbal instructions on how to perform PEF-monitoring self-measurement. Nurses or technicians can be responsible for supervising the test.

Prior to the actual recording, the patient should practise the forced expiration manoeuvre under supervision until the measurements are accurate. Careful instructions for the correct performance of the test are detailed in reference no. 17 (see below).

Briefly, subjects should be at rest. The test can be performed in a standing or sitting position, but the neck must not be flexed. Having taken a maximal inspiration, and after only a momentary pause at total lung capacity, the subject is to blow as hard as possible, maintaining an airtight seal between the lips and the mouthpiece, which should be gripped by the teeth. Dentures should not be removed unless they fit very poorly. Care should be taken not to squeeze or obstruct the orifices of the peak-flow meter with the fingers, and not to impede the progress of the pointer. Three technically satisfactory blows should be performed each time. At least two of the three should be within 20 l min of the other (9).

Ideally, the patient should record all three measurements, and the graph should be plotted by the nurse or technician. Ideally, subjects should not be asked to select the best PEF and should not plot the graph.

Measurements are reported on a diary card. Patients should be instructed to fill in the diary card carefully. In particular, medication taken, respiratory symptoms, and respiratory tract infections, as well as exercise and time going to and coming from work, should be reported every day. Moreover, any major change in the regular rhythm of life, unexpected events, and diseases should also be recorded (date and time of the day).

2.2. Frequency of assessment

The ideal frequency of daily assessment is debatable. Measurements are usually taken every 2 h during waking hours (2, 5, 9, 10, 13, 21) during periods at work and periods off work in order to detect short episodes of bronchoconstriction.

Some authors use a six-times-a-day assessment (12, 15). A recent paper compared graphs recorded every 2 h with a four-times-a-day recording (14). It was found that, although graphs of PEF recorded every 2 h have some advantages over less frequent recordings, e.g., optimal sensitivity and specificity, four-times-a-day assessment is almost as satisfactory, and may possibly result in higher compliance and most reliable readings (14). To enhance the re-

liability of four-times-a day assessment, which does seem more advantageous in clinical practice, a suggestion is to take measurements four times a day during waking hours regularly, the first one immediately on waking, plus additional measurements in the presence of symptoms (16).

It must be stressed, however, that the number of readings needed for analysis depends on the degree of changes seen due to work and the inherent instability of asthma. For those with obviously normal or abnormal records, two to three readings a day are sufficient. For those with variable asthma and smaller changes at work, more readings are better.

2.3. Period of self-monitoring

Periods at work are compared with periods off work. The duration of periods at work and off work differs depending on the author. Burge first proposed at least 1 week at work followed by 10 days off work followed by 2 more weeks at work (9) and thereafter (21) about 4 weeks at work. Other groups suggested three working periods separated by periods away from work with at least one of the periods off work longer than 1 week (2); yet others suggested 3 weeks at work and 2 weeks away from work (12, 15). Several authors use 2 weeks at work and at least 2 weeks off work (13, 14). It is up to the physician to judge the duration and the sequence of periods at work and off work for PEF monitoring. In general, there is a difference in the length of record required for somebody who has a normal PEF diurnal variation within the normal range (no asthma) and records where asthma is present with increased diurnal variation which is not so obviously related to work. In the former situation (no asthma), quite short periods can exclude occupational asthma; in the latter instance, much longer periods, including 2 weeks away from work, are required. In any case, periods at work should be prolonged enough to permit a careful evaluation of the pattern of response (see item 3.2.2) and to avoid false negative results due to a lack of exposure to the suspected offending agent(s), particularly when exposure is only intermittent. In some instances, this may take only hours, but before the conclusion of a negative recording is made, a 2-week period of monitoring at work under usual conditions is advocated. However, the period at work should be stopped when a significant pattern of occupational asthma is observed, as in this case there is no need to maintain exposure. Periods off work should be prolonged enough to allow for recovery, the start of which could be delayed and take a long time to complete (9).

To overcome one of the major problems of PEF self-monitoring, i.e., inadequate patient compliance, a favourable relationship between the nurse or technician and physician, and the patient is an important prerequisite. Patients are usually seen every 2 weeks and their records checked. However, if patients need to contact the nurse or technician more frequently during the measurement period, they should be encouraged to do so. In addition, patients should not feel obliged to alter their lifestyle due to the monitoring regimen, and it should be explained that being occasionally late or early for a measurement does not really matter as long as the measurements are recorded on the diary card.

3.0. Means of interpreting results

3.1. Summarizing PEF self-monitoring data

PEF readings are plotted on a graph where the x-axis represents days and the y-axis PEF l/min, the scale of the y-axis being identical for each subject. The graph is plotted on the diary card where days at work and off work are marked. Since days at work are not always identical, days of exposure to the suspected offending agent(s) can be indicated as well. Days should be taken as morning-to-morning periods rather than calendar days.

Graphs can be analysed qualitatively by simple visual assessment or quantitatively by calculating intraday and/or within-day indices of variability (13), comparing periods at work and periods off work.

3.2. Analysis and interpretation of PEF records

3.2.1. Visual analysis vs variability indices. PEF monitoring for long periods results in a bulk of data that are difficult to manage in clinical practice. Calculation of variability indices requires much time by the readers; besides, it is not clear which index is more indicative for a significant variation. Burge et al. (7, 8) first used visual assessment to analyse PEF monitoring data. They described several patterns of changes in PEF (see item 3.2.2), but did not give the quantitative change required for diagnosis. In subsequent works, they considered a record with a mean peak flow in the normal range and a diurnal variation of less that 15% as normal (21). Visual assessment is a more direct method of analysis, but it is based on subjective criteria and does not rely on any well-standardized ones. Despite this, recent studies have shown that visual assessment of PEF records is a satisfactory means of investigating occupational asthma due to various agents (13–15). With the specific challenge as the gold standard, visual analysis has been found to have higher sensitivity and specificity levels than various other objective PEF-derived indices. Only in western red cedar asthma (15) did the difference in mean PEF between the maximum PEF during weekends and the minimum PEF on working days have a sensi-

tivity greater than that of the visual assessment, and a similar specificity. Complete concordance between different readers in interpreting PEF graphs by visual inspection has been found in a percentage of cases varying from 69% (10) to 78% (13) and 82% (14). Therefore, visual analysis seems a satisfactory method for interpreting PEF data in most cases with typical patterns.

Difficulties in the visual inspection of PEF can arise when patterns are not typical (see item 3.2.2.), particularly when asthma is severe or when exposure to the offending agent is intermittent (22). In these cases, the interpretation of the monitoring may be difficult and requires careful case-by-case consideration. It is thought that the possibility of a more objective method of analysis based on the use of one or more numerical indices, such as moving average or exponentially weighted moving average (24, 25), should be explored.

3.2.2. Pattern of reactions emerging from PEF monitoring. Burge (9) described typical patterns of changes in PEF that are due largely to the speed of recovery: the hourly pattern, i.e., changes occurring from hour to hour within 1 day; the daily pattern, i.e., changes occurring from day to day within each work week; and the weekly pattern, i.e., changes occurring from week to week.

Changes within 1 work day (the hourly pattern) resemble the immediate and late response to a specific bronchial challenge (4). They are seen only when there is reasonable recovery by the next day. Repeated exposure often reduces this recovery, resulting in a flat pattern where the peak flow is depressed fairly uniformly for the whole day.

The daily patterns depend on the cumulative effect of repeated exposure and on the time it takes for recovery. Repeated daily exposure can result in an equivalent deterioration each day if recovery is substantial on the day after exposure. Equivalent daily patterns are usually associated with immediate asthmatic reactions and rapid weekend recovery. If recovery is incomplete by the day after exposure, repeated daily exposure can result in a progressive daily deterioration. Each day is worse than the day before. Sometimes a plateau is reached at the end of the week. Recovery is usually longer at the weekend. Daily patterns are only seen when there is substantial recovery during breaks (usually 2-day weekends).

When recovery takes longer than 2–3 days, the pattern that results (weekly pattern) depends on the time it takes for recovery to start and the worker's response to repeated exposure. The start of recovery is sometimes very delayed after a patient leaves work, and continues for a prolonged time (9).

3.2.3. Sensitivity and specificity of PEF monitoring. The sensitivity and specificity of PEF monitoring in diagnosing occupational asthma have been evaluated in most studies by visual assessment as a method of graph analysis and different gold standards. In the original works of Burge et al. (7, 8), using the combination of history and specific challenges as the gold standard, the sensitivity of visual analysis of PEF monitoring varied from 77%, in colophony-induced occupational asthma to 100% in isocyanate-induced asthma, while specificity was found to be 100% in both. In more recent studies (12, 13), with specific challenges as the gold standard, the sensitivity of visual analysis of PEF monitoring varied from 86% (12) to 81% (13), while specificity varied from 89% (12) to 74% (13).

One group evaluated the sensitivity and specificity of PEF monitoring, using diurnal variation $\geq 20\%$ when it was relatively more frequent or with greater variation on working days than days off work as the criteria for PEF interpretation of occupational asthma and a combination of history and/or changes in bronchial responsiveness to methacholine and/or skin test and/or bronchial challenges as the gold standard (23). In this study, the sensitivity of PEFR monitoring was found to be 72% and specificity to be 53%.

The poor sensitivity and specificity of PEF monitoring in some subjects, compared to specific bronchial challenges, can be explained by the lower sensitivity of PEF in detecting mild bronchial obstruction (16), particularly during the late response to occupational sensitizers (26). It is difficult to determine what percentage change in PEF would correspond to a significant change in FEV_1, but an attempt to identify a correspondence between PEF changes and FEV_1 changes in absolute values during bronchial challenges was made in a recent study (27).

Another possible explanation of the lower sensitivity and specificity of PEF monitoring is that prolonged monitoring requires strong motivation and good collaboration on the part of the subject; both can diminish over a long period, due to weakening compliance, fear of job loss, or malingering to receive compensation benefits (22).

In any case, these sensitivity figures result in a considerable percentage of false negative results, and it should be strongly emphasized that "stable" PEF does not exclude mild airway lability.

3.2.4. The problem of the "gold standard". As reported above, all the data of sensitivity and specificity of PEF monitoring have been referred to a gold standard, e.g., history with specific challenges, specific challenges alone, or a combination of various tests. As a matter of fact, all of these gold standards have shortcomings, and specific challenges, which at

present are considered the best gold standard (2, 5), can result in a percentage of false negative results due to technical or methodological problems. This could be a bias in evaluating PEF monitoring sensitivity and specificity data.

3.2.5. Association between PEF monitoring and measurement of nonspecific bronchial responsiveness. To improve the reliability of PEF monitoring and to provide more objective criteria for diagnosing occupational asthma, linking the measurement of nonspecific bronchial responsiveness to PEF self-monitoring at the end of a period at work and at the end of a period away from work has been suggested (11) and is widely used in clinical practice. However, two studies (12, 13) have shown that this does not improve either the sensitivity or the specificity of visual analysis of PEF. When changes in PEF are associated with parallel changes in nonspecific bronchial responsiveness, the diagnosis of occupational asthma is highly probable. If there is disagreement between PEF monitoring and nonspecific bronchial responsiveness, it may be prudent to do more testing (longer monitoring of PEF, specific bronchial challenges) to confirm the diagnosis.

3.2.6. Interference from therapy. Theoretically, an optimal PEF reading is taken where there is no therapy in progress. In practice, as many subjects are already undergoing therapy when they are referred for the investigation of occupational asthma, it is debatable whether treatment should be discontinued or not. In the original works of Burge et al. (8) and Burge (9), the use of antiasthmatic medications (steroids or cromoglycate) resulted in lower PEF sensitivity. By contrast, recent data have shown that the use of common antiasthmatic medications, both bronchodilators and inhaled anti-inflammatory drugs, does not affect the sensitivity and specificity of PEF readings determined using specific challenges as the gold standard (14). As a matter of fact, reduction of or changes in the usual therapy could be associated with a deterioration in asthma and a decrease in PEF upon the subject's return to work, and these could be erroneously interpreted as work-related. Therefore, a patient's usual medication, particularly inhaled steroids or theophylline, should not be interrupted or varied during monitoring, whereas inhaled $beta_2$-agonists should be taken only as needed (22) and reported on the diary cards. The important point is that treatment be the same at work and away from work (9).

3.2.7. Objectivity of PEF self-monitoring arbitration. All the assessments performed are based on subjective judgement and/or empirical experiences, fixed days or percentages in or for which a certain parameter has to be lower in the work period than in the off-work period, although this is not entirely justified. Attempts have therefore been made to apply methods of trend analysis (moving average or exponentially weighted moving average) (24, 25) to interpreting PEF-monitoring data, taking into account all the measurements during both periods. Based on the pool of data collected during the off-work period, the criterion is set for a significant change of the values during the at-work period, allowing for an objective assessment of records.

4.0. Advantages of PEF self-monitoring

1) ability to assess patient's lung function outside the laboratory, in a natural setting, at work, at night, and on weekends and holidays
2) simplicity of PEF measurements; manoeuvre by means of cheap and handy devices
3) usability in nonspecialized centres where specific challenges cannot be performed
4) usefulness in differentiating between nonoccupational and work-related asthma
5) If specific bronchial challenges are negative due to a worker's being away from work for too long, then serial PEF provides a means to prove the relationship between asthma and workplace.

5.0. Limitations

1) Patient motivation and honesty are a crucial prerequisite, and lack of this prerequisite can often be a serious hindrance or aggravation in compensation-oriented patients. Compliance could be low due to the frequency of daily assessment or a loss of interest caused by the long period of monitoring (4 or more weeks). Patients of low intellectual ability can encounter serious difficulties. The new instruments available for storage data, thereby preventing falsification of data, may overcome these disadvantages.
2) Re-exposure of the patient to the work environment is necessary, and could be potentially dangerous.
3) It takes a relatively long time to obtain the results (long duration of the recording period before a reliable assessment can be made).
4) There are organizing difficulties – arranging for the off-work period can mean that the monitoring period shifts for several months and delays the end of the diagnostic protocol and operative decisions.
5) Under certain circumstances, the need for the patient to be at work can be a major drawback – if the patient is not operating any more, if the worker is not employed any more, or if the technology has changed, monitoring cannot be per-

formed (requests for compensation claims require re-evaluation).

6) There are interpretation difficulties: reading of PEF plots is not objective; there are uncharacteristic patterns and borderline results.
7) The poor sensitivity of PEF self-monitoring leads to a high percentage of false negative results.
8) PEF self-monitoring can confirm the relationship between symptoms of asthma and occupational exposure, but it cannot relate the asthmatic condition to a specific agent unless one deals with a worker exposed to one agent only and with significantly increased specific IgE antibodies (generally high-molecular-weight agents). Therefore, generally, the method cannot distinguish between occupational asthma, i.e., asthma caused by a specific agent present at work, and so-called work-related asthma, i.e., bronchoconstriction induced by nonspecific exposure to irritants in the workplace in a subject with bronchial hyperreactivity.

6.0. Recommendations

PEF monitoring is a satisfactory tool for providing objective evidence of work-related asthma. However, work has to be done in the following areas:

1) instruments that can record PEF and FEV_1 and store the data, with accurate recording of flow rates
2) further studies on the required frequency of daily assessments
3) computer programs to generate graphs in a standardized way
4) more objective ways to analyse graphs other than "eyeballing" (visual analysis); such graphs would not require interpretation by a specialist or a physician; they could be interpreted automatically via a computer program, although the diagnosis would remain the physician's interpretation and responsibility
5) further studies comparing the results of specific inhalation challenges and serial PEF monitoring in subjects exposed continuously and intermittently to an offending agent at work
6) further studies to assess the effect of therapy (anti-inflammatory preparations) on the results
7) the applicability of the method to epidemiologic studies ("field studies") as opposed to an individual clinically-oriented approach.

These issues should be addressed in multicentre international studies.

7.0. Conclusions

PEF monitoring is a reliable method for confirming the relationship between occupational exposure and symptoms of asthma. It is feasible in nonspecialized centres, and it is simple and safe to perform. Nevertheless, and it is time-consuming and requires collaboration and honesty on the part of the subject.

Analysis of PEF graph-derived data is still based on subjective evaluation, and the development of more objective methods of analysis is needed.

The interpretation of PEF data in diagnosing occupational asthma is a critical point, and it should be carefully considered in every case. PEF monitoring could be useful as a first-level confirmation of a history of suspected occupational asthma in nonspecialized centres, but the interpretation of PEF data for confirming a diagnosis of occupational asthma should be referred to a specialized centre. The low sensitivity of PEF monitoring means that there is a considerable percentage of false negative results, so a "stable" PEF does not exclude the presence of occupational or work-related asthma. However, even in the case of a pattern of PEF monitoring indicative of a positive relationship between symptoms and occupational exposure, it should be emphasized that PEF monitoring cannot relate symptoms to a specific agent. Thus, PEF monitoring is not useful in aetiological diagnosis, except in the minority of cases of occupational asthma where there is a clear demonstration of specific sensitization (i.e., strongly positive for IgE antibody) to agents present at work (2). In these cases (for instance, bakers), a strongly positive peak-flow record associated with a strongly positive IgE antibody assessment is sufficient to make a precise aetiological diagnosis.

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