ASSOCIATION OF RESPIRATORY TECHNICIANS AND PHYSIOLOGISTS

VOLUME NO 32 NOVEMBER 1987

BREATH

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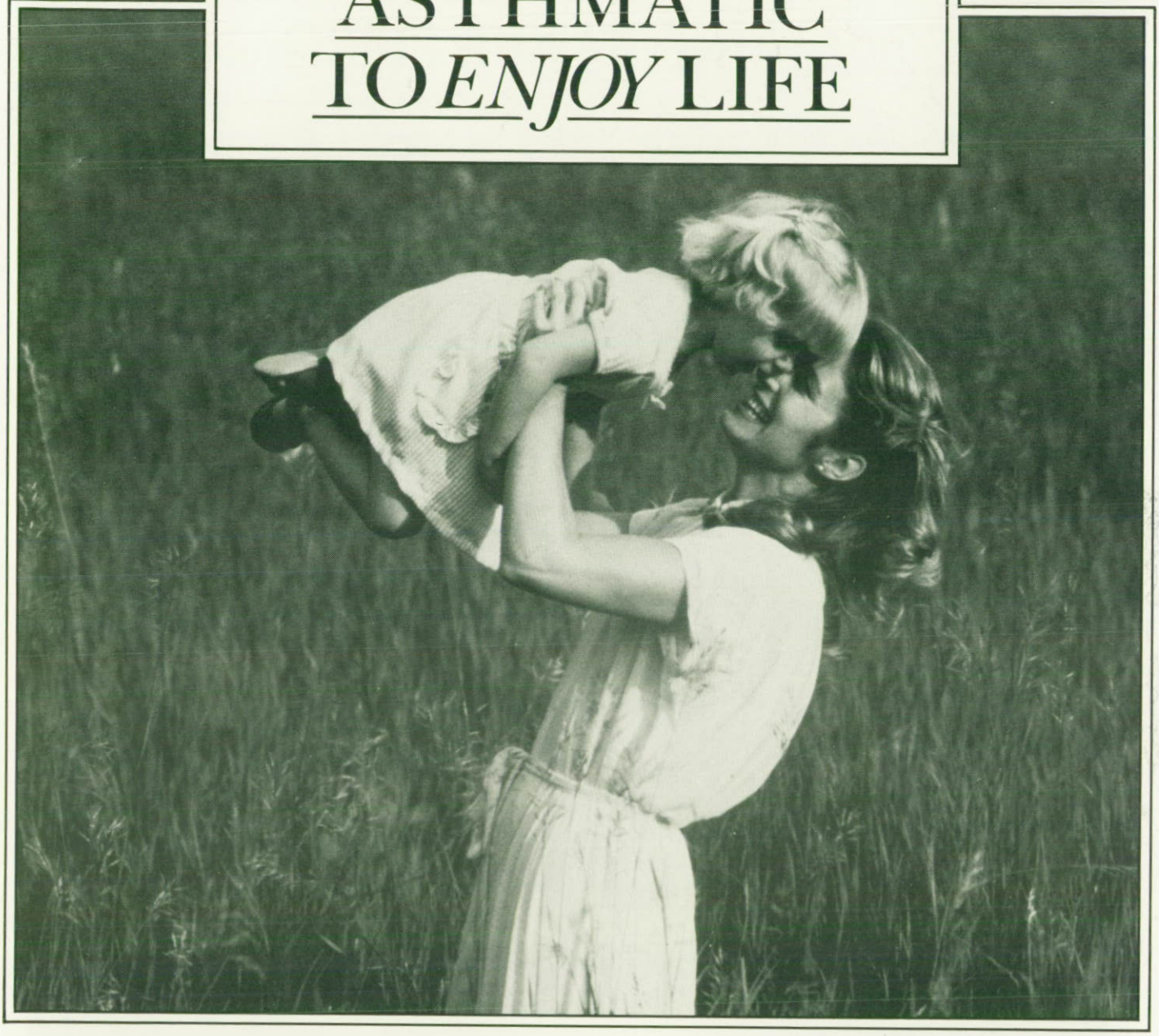

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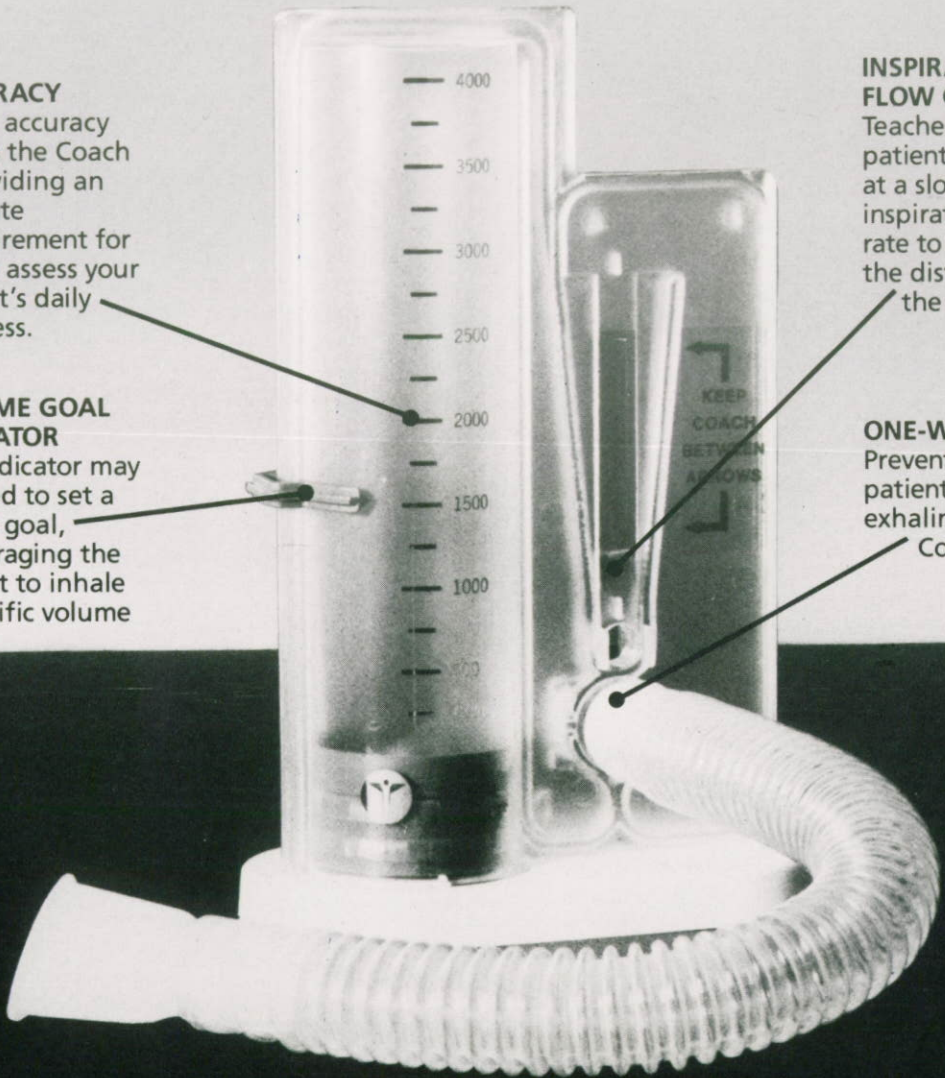

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EDITORIAL

COMPUTERIZATION OF LUNG FUNCTION EQUIPMENT — THE ANSWER TO ALL OUR PROBLEMS?

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Bristol Royal Infirmary

Today, the sophisticated pocket calculator and the computer are accepted as part of everyday life. Many of us in pure and applied science would probably be left floundering in a sea of figures and complicated equations if computers were suddenly removed from our lives. They allow us to solve complicated mathematical problems, to analyse large volumes of data and to perform repetitive calculations. Perhaps more importantly in this age of supersonic flights, rapid communications and the constant pressure upon us to increase efficiency and to provide better services, computers theoretically allow us to save time.

The advent of computers in respiratory laboratories has been, until recent years, a slow process. Although computers were available to respiratory technicians and scientists, they were, in the past, bulky devices and had a limited role in everyday laboratory practice. However, with the decrease in size and cost the advancement of the computer in respiratory laboratories is such that today it is becoming increasingly difficult to buy any piece of equipment without a computer lurking somewhere among the packages.

This increase in computers has partly been caused by pressure from manufacturers who have seen the so-called advantages of having a computer in the department, and partly by the gullibility of heads of department who rather like the ideal of possessing a computer. However, probably the most important factor lies across the Atlantic Ocean, where computers and computerized systems seem to have become the be-all and end-all of life.

The advantages of having a computerized system apparently far outweigh the disadvantages (1). The advantages are seen as: 1) complete automation may result in a reduction in time and cost with an increase in accuracy; 2) assurance that standardized procedures are followed; 3) a reduction in major measurement errors; 4) storage and retrieval of information quickly and efficiently; 5) implementation of automated calibration and system checks within the instrument; and 6) standardized and consistent interpretation of results. On the other hand, the disadvantages are seen as: 1) higher initial financial outlay; 2) more careful training of personnel; 3) limits in flexibility of some testing procedures; and 4) inability of the user to update and correct the software.

Are these advantages and disadvantages real of perceived? I propose to look more closely at this problem in an attempt to answer the question posed by the title of this article.

The Advantages

Time, Cost and Accuracy: The American Thoracic Society cautiously states that automation may reduce costs, save time and improve accuracy. Clearly even they are not sure. The higher initial cost of purchase and installation and the need for additional training in computer literacy need to be seen in the light of any real savings achieved from the use of a computerized system. For instance, body plethysmographs now have software packages that will collect the flow, mouth pressure and box pressure data, estimate the position of the slope of the airways resistance and thoracic gas volume loops, allow the operator to reposition the computer drawn lines and will then calculate the results. Real or perceived saving? I believe that in this instance the savings are merely perceived. A skilled technician or scientist is able to draw precise lines through the loops at the first attempt, without having to waste time checking and if necessary, repositioning the computer drawn lines. Typing the angles of the lines into an independent computer will quickly produce the results. Actual savings are therefore probably little if any.

Improvement in accuracy? Operators will be strongly tempted to assume that the lines drawn by the computer are the most appropriate and that the results will therefore be the most accurate possible. It should be remembered that the computer is only as "clever" as the program written for it! Each computer plot needs to be carefully checked before being accepted, with poor quality loops being rejected, and incorrectly positioned lines repositioned appropriately. Even then this may not be as accurate or as reproducible as a skilled operator drawing the lines by hand. Thus, apparent increases in accuracy may not in reality always be valid.

Standardized Procedures: The assurance that standardized procedures are followed may be correct for some tests such as spirometry or gas transfer factor. For body plethysmography, this would appear not to be so. Available software allows the operator to plot the lines in a variety of "recognized" ways, but with a further option of allowing the operator to choose the plotting criteria. This is certainly, in one sense, a flexible piece of software, but hardly standardizes the methodology. This degree of flexibility may be quite acceptable, but a particular difficulty results when trying to reproduce other workers' data. Often the piece of equipment is quoted without specific details of the plotting procedures being given. Ultimately, this will lead to conflicting data being produced rather than solving specific problems.

Reduction of Errors: Certainly the use of a computer for repetitive or complicated mathematical problems will significantly reduce the sources of error. If data is collected by the computer directly from the measuring device, the operator is unable to make transcription errors — a common source of error. This of course assumes that the software and hardware are working correctly, which may not always be the case (2). All software and hardware should be thoroughly validated before final commission and thereafter regular checks should be made to verify acceptable performance (1).

Data Storage and Retrieval: Probably the greatest theoretical advantage of a computer is its ability to store and retrieve information quickly and efficiently. Certainly a considerable amount of space is saved when compared

with that required for paper-stored data. However, storing data on disks or magnetic tape does create problems, the greatest of which is the potential accidental loss of large amounts of data stored on a single mass storage medium. It is therefore necessary to maintain at least two complete sets of regularly updated copies of all data and programs, which should be stored safely to prevent inadvertent destruction. Even so, paper copies of the original data should be maintained. Thus the overall cost of using a computer in this way increases with no real savings in floor space. Indeed, a good, well maintained paper file is just as efficient. Another problem is patient confidentiality, which must be maintained at all times and requires the setting up of special security codes such that only designated personnel have access to the data.

Automated Checks: The use of automated calibration and system check procedures is, in theory, a useful application of computers, particularly since many people regard quality assurance as a monotonous chore. In practice, close attention needs to be paid to what the software and hardware are actually doing. For instance, when the computer calibrates a gas analyser, is it performing a two-point or a multi-point calibration? Can the software actually do both? Is it calibrating the analyser or the computer? A gas analyser needs to be calibrated on a daily basis and this should consist at least of a two-point calibration over its working range. However, this does not assess the linearity of the analyser, which needs to be checked regularly otherwise significant errors may result (3). This of course assumes that one can actually gain direct access to the analyser. Operators must never be lulled into a sense of false security and assume that the system is being calibrated automatically. The need for quality assurance should never be ignored, and the use of physical standards and "test subjects" should never be replaced by computer calibrations.

Interpretation of Results: The maintenance of standardized and consistent interpretation of results assumes the computer has been programmed to interpret the results. Although some users (4,5) find this approach useful, it provides a physiological, not a clinical report. The final interpretation is left with the physicians, and trying to get them standardized so that consistent interpretations occur may be rather difficult!

The Disadvantages

Cost: The purchase of a computer inevitably adds to the initial cost of the equipment, and the software, cabling and other items will entail further outlay. This may well be acceptable, but what of the future? Consumables such as additional disks (hard or floppy), printer ribbons and computer paper need to be taken into account. There must be adequate facilities for storage of printouts of all software and its validation and of disks and their copies. The latter should ideally be stored in a fireproof safe. Maintenance costs should be borne in mind. The less obvious costs may include the need for specific furniture, antistatic mats, antiglare screen guards and printer hoods to reduce printer noise. It may well be tempting to spend an extra £2000 on a computerized system, but the expenditure will not stop once the initial purchase has been made.

Training: The need for more careful training may not at first be obvious. After all, following the instruction manual should, in theory, allow the operator to use the equipment and obtain the required results. However, this attitude will lead to disaster. Technicians will simply be required to push buttons and generate numbers. They may not fully understand what the equipment is doing, how it is doing it or whether it is functioning correctly. Perhaps more importantly they may not understand the principles of the tests and the theory behind them. If we are to accept this "push-button" age, and I believe we should not, then technicians must be trained to a very high standard, not only in the performance of the tests but also in their understanding of the theory behind them.

Software Flexibility: Computer software needs to be very flexible, to encompass both normal subjects and extremely dyspnoeic patients, who may be unable to perform the tests in the prescribed manner or within the time limits imposed by the software. In such circumstances, results may often be obtained very satisfactorily from manually processed measurements. The current trend, however, seems to be towards systems which cannot function without a computer. This puts the onus on the manufacturers to ensure that their software is flexible enough to encompass the wide variety of subjects who need to be tested.

Difficulties may still arise. A system which can only be run by a computer means that it will become impossible or very costly to perform the more esoteric lung function tests, which do not form part of the routine test package. For those in research, the development of new techniques, or the modification of old techniques may well be frustrated by the need to be computer literate.

Computers, like all other instruments, are subject to malfunctions. If the computer runs all the equipment and it fails, the laboratory is left with expensive equipment which cannot be used. At lease if a system can be both manually run and run by the computer, this problem would be obviated.

In reality, it is likely that compromises must be made in the software and that programs are flexible up to a point. There is, however, in my opinion, no justification whatsoever for manufacturers producing equipment that can only be run by a computer. All manufacturers should ensure that they produce equipment which can be both manually operated and run by a computer.

Software Correction and Update: Complex software will often contain minor errors, which may easily go undetected unless careful evaluation of the system is performed (1,6). Errors that are found need to be corrected quickly. However, pinpointing such errors, even for a software specialist, may be difficult since many manufacturers are reluctant to provide even the basic details of how their software works. The onus is therefore on the manufacturer to provide a very rapid service for correction and updating of software. The provision of more details of the software would be of benefit to both the user and the manufacturer in rapid diagnosis and correction of faults. Furthermore, the provision of test data used by the manufacturer to assess the performance of their equipment is needed by the users.

Conclusion

I have attempted above to raise some of the issues concerning the computerization of respiratory testing equipment. Whether we like it or not computers now infringe on almost every aspect of our daily lives. But do we want or even need computers in respiratory laboratories? I believe it is inescapable that computers now form, and will continue to form, part of the everyday running of respiratory laboratories. Their precise role is more questionable. The calculations of many lung function tests are certainly made easier by computers and the production of a final quantitative report is a useful application (7). The on-line collec-

tion of data during a test procedure has advantages, but does not replace the need for the traditional paper recordings. Running the test procedures and the laboratory by computer is somewhat more questionable and has far wider implications. What is the future status of technicians who simply push puttons for a living? What are the implications for training standards? These and many more questions should be addressed by all of us and given very careful thought. The users should ultimately decide, and should not simply accept what the manufacturers sell in pretty space-age packages or what heads of department think the users would like.

It is up to each department as a whole to decide on what it wants, within the financial constraints placed upon it. Heads of department should listen to their experienced technicians before making what could turn out to be costly decisions. Guidelines are available on quality assurance (6) and on the application of computers (1) and should be used. Never be persuaded by manufacturers, who should be selling what we want, not what they think we want.

I believe that the computer does have a role in a lung function unit, albeit limited. To answer the question posed in the title, I think at present that many more problems are created by computerization of lung function equipment. Computerization is not the answer to all our problems; it simply solves some problems whilst creating further problems.

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SLEEP DISORDERED BREATHING AND SCREENING TECHNIQUES

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Summary

The sleep apnoea syndrome is a bizarre symptom complex with considerable morbidity and mortality, characterised by recurrent apnoeas during sleep. These patients are often referred to chest physicians for assessment and the numbers will increase as the medical and general public become more aware of the variety of respiratory problems that may occur during sleep.

To prevent the few centres which regularly perform sleep studies from becoming overwhelmed some simple screening procedure is required at District Hospital level. This would enable a diagnosis of probable sleep apnoea to be made before referral to a specialist centre for further evaluation and treatment. Several methods of screening have been suggested but experience dictates that most information is obtained from the continuous overnight measurement of arterial oxygen saturation.

Introduction

The sleep apnoea syndrome is a varied symptom complex produced by recurrent and often prolonged episodes of inadequate ventilation during sleep. The typical features (Table 1) have been recorded in literature for many years and are best described by Charles Dickens in his first published book, "The posthumous papers of the Pickwick Club." Here Dickens describes a fat boy, Joe, who was excessively sleepy, snored loudly and suffered from dropsy (heart failure). In the mid 1950's the term Pickwickian syndrome was coined for obese patients with cor pulmonale who were sleepy and polycythaemic. The underlying mechanism for the symptoms was discovered in the early 1960's when periods of irregular respiration (apnoeas or hypopnoeas) were observed during sleep (1). If a tracheostomy was performed the irregular respiration ceased and their symptoms dramatically improved suggesting a problem in the upper airway. With technological advances in recording electroencephalograms, nocturnal oxygen saturation and ventilation, detailed assessments were possible which allowed characterisation of sleep apnoea.

The sleep apnoea syndrome has an incidence between 1 and 10% in North America, occurring in young and middle aged men, post-menopausal women and the elderly (2). In Britain the incidence appears less, although detailed epidemiological studies are awaited.

Table 1

Clinical features of sleep apnoea syndrome

Frequent movements during sleep	100%
Loud snoring (often long history)	84%
Excessive daytime sleepiness	78%
Personality change or reduced intellect	50%
Sexual problems	50%
Morning headaches	36%
Bed wetting	30%

Fifty patients, (48 males) aged 28-62 years (2).

Mechanism of Apnoeas

An apnoea (defined arbitrarily as no airflow for 10 seconds) or hypopnoea (reduced airflow with associated arterial desaturation) can be classified into two broad groups depending on respiratory muscle activity. Central apnoeas occur if there is inadequate muscle activity, whereas obstructive apnoeas occur in the setting of normal and often increased respiratory movements. Obstructive apnoeas are more common and produce the typical symptoms as listed in Table 1.

Apnoeas occur because of reduced pharyngeal muscular activity during inspiration. As a patient with sleep apnoea drifts into sleep, tone in the upper airway decreases, relatively narrowing the lumen, increasing resistance and producing turbulent flow (snoring). Because of the Venturi effect pressure distal to the obstruction falls, sucking in the relatively unsupported pharyngeal tissues and further occluding the lumen. This vicious circle, compromising ventilation, continues until arousal occurs, when return of pharyngeal muscle tone terminates the apnoea, usually with a characteristic "grunt", referred to by the bed-partner as a loud snore. The cycle is repeated throughout the sleeping period, producing frequent body movements, recurrent arterial hypoxaemia, and destroying sleep architecture with subsequent excessive daytime sleepiness. During Rapid Eye Movement (REM) sleep there is a generalised reduction in muscle tone and arousal thresholds are increased, therefore apnoeas during REM sleep are longer and associated with greater arterial hypoxaemia (3,4).

Treatment

Although the natural history of sleep apnoea is not fully established, it is associated with considerable morbidity and probably mortality; therefore some form of treatment is usually necessary. Weight loss and avoidance of hypnotics, including alcohol should be tried initially, but are often unsuccessful. Oral drugs, including protriptyline, almitrine and medroxyprogesterone acetate have been tried with variable success, side effects often limiting the dose. Continuous positive airways pressure (CPAP) applied to the face appears considerably more successful although it is cumbersome, has to be used regularly and some patients find wearing the tight fitting mask intolerable. Tongue retaining devices and attempts at changing sleep position rarely contribute to management.

Surgery is often helpful, especially if the upper airway lumen is narrow. Removal of local obstructing lesions, eg enlarged tonsils or increasing the upper airway diameter by means of a pharyngoplasty may be successful, depending on patient selection and surgical technique. The therapeutic options will not be discussed further in this paper but details can be found in several texts on sleep disordered breathing (2,5).

Investigations

Investigation of suspected sleep apnoea is difficult, time consuming and expensive. A full history with discussion of the patient's sleep pattern with the bed partner followed by clinical examination with special reference to the cardio-respiratory system and appearances of the upper airway will confirm that further investigation is required. Such investigations can be classified as:

General — providing background information on the patient, as in Table 2.

Table 2
Background investigations

	For detection of
Haemoglobin, packed cell volume	Polycythaemia
Chest X-ray	Cardiomegaly
Electrocardiogram	Myocardial infarct Arrhythmias
Arterial blood gases	Awake hypoxaemia Hypercapnia
Serum thyroxine or TSH	Hypothyroidism
Flow volume loop	Extra thoracic airflow obstruction Saw tooth sign
Lung function tests	Lung disease
ENT opinion	Evidence of obstructing masses

Definitive — Allowing full assessment of the nature and severity of any apnoeas which may occur. For a definitive study the measurements required are shown in Table 3.

Definitive investigation may be performed during the day via a nap study (6). Although convenient, some patients cannot sleep during the day and prior sleep deprivation may artificially increase the number of abnormal respiratory events. More importantly REM sleep may be absent, underestimating the severity of apnoeas and arterial desaturation, so an overnight study is usually required. For the patient this involves sleeping in a strange bed with considerable monitoring equipment attached. Needless to say sleep is often disturbed in normal people and a "run in night" is suggested although in patients with sleep apnoea this is rarely necessary. To observe both patient and equipment a trained technician has to remain vigilant throughout the night with medical personnel available if problems arise.

Running a sleep laboratory is expensive. Capital expenditure on equipment is considerable, the major outlay being the recording system used, which may be instrumentation tape, paper or computer based. The latter allows some real time analysis to be done, thus saving technicians from the time consuming chore of reading traces manually. Further costs to be considered are specific monitoring devices such as oximeters, movement detectors (eg "Respitrace") and "disposables" such as electrodes, paper and ink.

Table 3
Definitive investigations

Airflow at nose and mouth	Presence of apnoeas
Chest and abdominal movement	Nature of apnoeas
Electrocardiogram	Cardiac arrhythmias
Oxygenation (SaO_2)	Degree of hypoxaemia
Electroencephalogram Eye movements Muscle tone	Sleep stage (especially REM)

All signals are amplified and recorded simultaneously on paper or instrumentation tape for later analysis or by computer, allowing real time interpretation.

At present respiratory problems during sleep are not recognised at Governmental or Regional levels. Therefore funding for the dozen or so sleep centres in Britain is usually through research grants and few doctors have access to sleep studies. As public and medical awareness of problems during sleep increases the demand for sleep studies will rise, further stretching the limited service.

Indications for performing sleep studies need to be defined. In North America where studies are widely available, indications are broad (7). In Britain, with our limited resources we need to be selective, studying patients who have a high probability of suffering from sleep apnoea (Table 4).

Table 4
Indications for sleep studies

1 *Sleep apnoea — absolute indications:*
- Excessive daytime sleepiness
- Apnoeas observed by bed partner
- Suggestive non-specific symptoms (see table 1)

2 *Sleep apnoea — relative indications:*
- Loud snoring
- Unexplained cor pulmonale
- Unexplained erythrocytosis
- Abnormal nocturnal ECG or hypertension
- Obesity

3 *Hypoventilation*
- Chronic bronchitis and emphysema
- Cystic fibrosis
- Restrictive lung diseases
- Neuromuscular diseases

4 *Nocturnal myoclonus*
5 *Narcolepsy*
6 *Insomnia*

Modified from (7).

Screening Procedures
Some form of screening technique should be available, to identify patients who need to proceed to full sleep studies. Ideally the screening procedures should be relatively cheap and thus widely available in most hospital centres, easy to use and durable. It should be comfortable, so that sleep is not disturbed, produce accurate reliable results, be sensitive and specific, giving some indication of apnoea severity which will dictate urgency of referral. Several methods of screening for sleep apnoea have been suggested and they will be discussed further.

Patient Observation
This is undoubtedly the simplest screening procedure and will confirm the diagnosis of severe sleep apnoea syndrome. The patient may sleep in a waiting room prior to consultation and the apnoeas may be noticed with the classical "grunt" as the airway reopens. Progressive cyanosis during the apnoea will confirm they are hypoxaemic, although its magnitude is difficult to estimate. Observation of patients in hospital overnight by nursing staff may also give an indication that they are suffering from sleep apnoea.

The major drawback from simple observation is the failure to obtain any objective measurements of severity, making it difficult to determine response to treatment.

Flow Volume Loop
A flow volume loop is available in most pulmonary function laboratories and has been advocated as a good screening procedure for sleep apnoea. Evidence of variable extrathoracic airways obstruction, described by the ratio of forced expiratory flow at 50% vital capacity to the forced inspiratory flow at 50% vital capacity (FEF_{50}/FIF_{50}) being greater than unity. Approximately 35% of patients with obstructive sleep apnoea, especially if there is evidence of upper airway obstruction (e.g. pharyngeal web) will have an abnormal flow volume loop. A ratio of greater than unity correlates with the severity of arterial desaturation but not with the number of apnoeas. Following successful treatment the ratio may fall, but it is only a crude guide (8).

The second abnormality seen on a flow volume curve is the "saw tooth sign," an uncommon oscillation of flow in the mid vital capacity region on both inspiration and expiration. The appearances are not well defined and therefore interpretation is open to subjective error, reducing its usefulness. The "saw tooth sign" was thought to be an ideal screening investigation for sleep apnoea with a sensitivity of 85% and specificity of 100% (9). Unfortunately subsequent work showed a sensitivity of less than 50% but the relatively high specificity remains if several observers agree on its presence.

By combining both the "saw tooth sign" and FEF_{50}/FIF_{50} ratio of greater than unity from flow volume loops obtained in the sitting and supine position, a sensitivity of over 70% for detecting sleep apnoea may be achieved, but with a relatively low specificity. Because of significant false positives the flow volume curve is an inadequate screening tool although the finding of the saw tooth pattern by several observers in a patient with suggestive clinical features is an indication for further investigation (10).

Laryngeal Sounds
Air flowing through the glottis produces turbulent flow and therefore noise. By fixing a microphone to a stethoscope bell taped to the neck these sounds may be recorded. With high and low frequency filtering to remove cardiac and background noise the quality of the recordings is further enhanced allowing periods of apnoea to be detected. With correct calibration hypopnoeas may also be evident and the loud "grunt" as the apnoea terminates is obvious (11).

The technique is especially useful in children who poorly tolerate face masks, thermistors and other methods of airflow detection (12). A simpler method is to put a microphone in the suprasternal notch and record the laryngeal sounds on tape. This can then be played back at a fast speed, making periods of apnoea obvious. Again the problem of using a laryngeal microphone is that little information is obtained on the severity of the condition.

Electrocardiograph (ECG)
Changes in cardiovascular function during obstructive apnoeas are well described and include elevation of systemic and pulmonary blood pressure, fall in cerebral blood flow and a variety of arrhythmias. The latter may include recurrent ventricular premature beats, tachycardias, bradycardia, sinus node arrest and atrioventricular conduction defects (13). These may be detected by 24 hour ECG monitoring but are not at all specific, occurring in normal individuals and in patients with ischaemic heart disease.

The sensitivity of 24 hour ECG monitoring is increased if cyclical variations in heart rate are found. During an

apnoea, bradycardia may occur followed by tachycardia at the end of the apnoea. If there are recurrent apnoeas a cyclical variation in R-R interval may be detected by computer analysis. This technique was evaluated in 362 patients with proven sleep apnoea and found to be sensitive, provided the apnoeic episodes were longer than 30 sec. The presence of marked R-R variation (over 30 beats per min) relates to the duration of apnoea in REM sleep and the magnitude of hypoxaemia, giving some indication of severity. The cyclical variations are not found in patients with autonomic neuropathy and are slight in those with central sleep apnoea, increasing the false negative rate of this technique (14).

Use of 24 hour ECG monitoring in screening for sleep apnoea is limited in Britain but our own experience suggests it is less useful than documented in North America.

Arterial Oxygen

Hypoxaemia due to recurrent apnoeas produces many of the clinical features found in the sleep apnoea syndrome (15,16). If profound falls in arterial oxygen tension (PaO_2) occur, prompt treatment is necessary, some centres recommending tracheostomy (17). Therefore measurement of PaO_2 is a good screening procedure but needs to be recorded continuously, excluding direct arterial sampling. A transcutaneous oxygen electrode estimates PaO_2 closely but the temperature required to produce accurate results frequently damages the skin, limiting its usefulness for overnight recordings. A further problem is the slow response time and the rapid fluctuations in PaO_2 which occur with recurrent apnoeas may be missed because of the time for the oxygen to diffuse through the skin.

The alternative non-invasive method of measuring PaO_2 is by ear or finger oximetry. The results from measured arterial oxygen saturation (SaO_2) are reliable until the saturation falls below 70% when they become increasingly inaccurate. Oximeters are available in many anaesthetic and respiratory physiology departments and recent models have a built in microprocessor which stores up to eight hours' information and provides a simple analysis. The probe itself is a lightweight device which clips to the earlobe or finger and interferes little with sleep.

If SaO_2 is displayed using a pen recorder at a slow speed a characteristic pattern is found in patients with severe sleep apnoea, (Fig. 1). With the onset of sleep, apnoeas occur which produce arterial desaturation; when the apnoea is terminated ventilation resumes and arterial oxygen saturation returns to its baseline value. If this process occurs throughout the night a broad line is produced reflecting

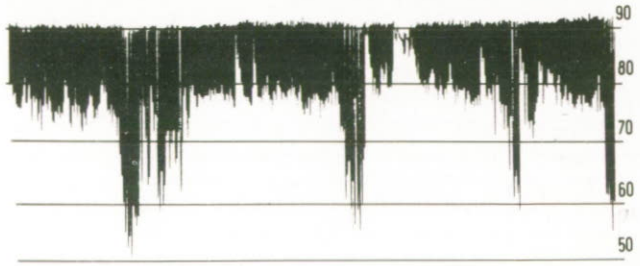

Fig. 1. *Characteristic appearances of severe obstructive sleep apnoea. Thick base line representing recurrent arterial desaturation with profound falls during REM sleep. (See text for details)*

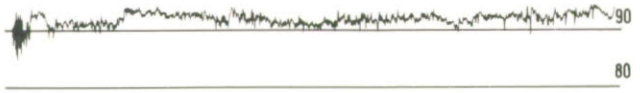

Fig. 2. *Same patient as fig 1 treated with CPAP.*

the recurrent arterial desaturation and subsequent resaturation. As can be seen in Fig. 1 there are periods when the SaO_2 falls to lower levels and these correspond to periods of REM sleep when the arousal threshold is increased and desaturation is greater.

This method of screening for sleep apnoea is sensitive and provides considerable information on the severity of hypoxaemia associated with the apnoeas and therefore urgency of treatment. It can also be used for assessing response to treatment as shown in Fig. 2, which shows the same patient following CPAP. The thick base line can be seen at the far left of the trace as the correct pressure for terminating the apnoeas is achieved, the thin line reflecting the absence of arterial desaturation. Some patients with mild sleep apnoea who have little arterial desaturation may not be detected by this screening procedure, but they rarely have cardiac problems and do not require treatment.

Patient with chronic bronchitis and emphysema of the "blue and bloated" type, cystic fibrosis and neuromuscular disorders also show arterial desaturation during sleep, (especially in REM sleep) but the characteristic broad thick pattern of the trace is absent (Fig. 3).

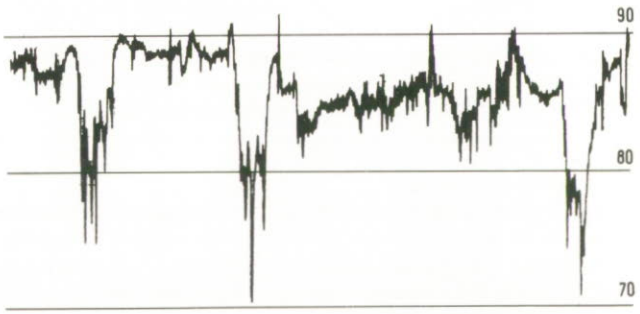

Fig. 3. *Trace from patient with chronic bronchitis.*

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VARIABILITY IN A SET OF FEV_1 MEASUREMENTS IN RELATION TO BRONCHODILATOR RESPONSE

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Summary

The variability in a set of routine forced expiratory volume (FEV_1) measurements was determined in 327 patients with airways obstruction and in 41 healthy hospital volunteers. The initial FEV_1 ranged from 0.3 to 5.05 litres. The variability expressed in absolute terms was similar at all levels of the FEV_1, but decreased with increasing FEV_1 when expressed as a percentage change. An absolute change of 180 mls is necessary to establish with 95% confidence that a change in FEV_1 has occurred other than by chance in a particular individual. A significant change in FEV_1 can therefore be defined by a single absolute value that is valid at any FEV_1; this may be more reliable than a percentage change when distinguishing between natural variability and the response to an inhaled bronchodilator.

Introduction

The change in FEV_1 which results from the administration of a bronchodilator drug is clearly of great importance in respiratory medicine. If this change is to be correctly assessed, then the natural variability of routine FEV_1 measurements needs to be ascertained for the type of patient in question. A number of reports have appeared on this topic (1-5) and there has been some debate on whether absolute or percentage changes should be used as the criteria for significant bronchodilator response. The aim of the present study was to establish the natural variability of FEV_1 measurement, by the methods in use in this laboratory.

Methods

A retrospective analysis of the FEV_1 measurements was performed in 327 patients selected for various levels of FEV_1 and with varying degrees of obstruction, who had attended for routine pulmonary function testing within the last 18 months and in 41 healthy hospital volunteers who had no history of asthma, hay fever or chronic bronchitis. An obstructed patient was defined as having an FEV_1 /FVC ratio lower than two standard deviations from the predicted normal value. The normal values and ranges were derived from Berglund et al (6). The forced vital capacities were measured using a water filled spirometer, the Spirotec (P K Morgan) which is fitted with a low torque potentiometer output for electronic data processing using the Spiro Data Dec (P K Morgan).

Each subject had data recorded for the best three attempts at a forced vital capacity which had been technically acceptable and the FEV_1 measurements from this data were used in the analysis. The results were divided into groups according to their FEV_1 to allow comparison of variability at different levels. The first subgroup of obstructed patients had an FEV_1 of < 0.5 litres, and then the patients were grouped at intervals of 0.2 litres (0.5-0.7, 0.7-0.9, 0.9-1.1, etc.) up to an FEV_1 of 3.1 litres, with a subgroup of normal subjects whose FEV_1 lay between 3.1 litres and 4 litres, and a further group of normal subjects with $FEV_1 > 4$ litres.

The variability in the FEV_1 was expressed for each individual subject, both in absolute terms as the standard deviation (S D in ml) from the mean (M) of the largest and smallest FEV_1 from the three attempts and in percentage terms as the coefficient of variation (V) where $V = 100\,(S\,D)/M$. The difference between these two FEV_1 measurements was used in the analysis because the response to a bronchodilator is also based on the difference between two values, the largest FEV_1 prebronchodilator and the largest FEV_1 post-bronchodilator.

Table 1

Mean coefficient of variation (%) and Standard deviation (ml) as the variability in FEV_1 against the mean FEV_1 within each subgroup.

FEV_1 Interval (Litres)	<0.5	0.51 – <0.7	0.7 – <0.9	0.9 – <1.1	1.1 – <1.3	1.3 – <1.5	1.5 – <1.7	1.7 – <1.9	1.9 – <2.1	2.1 – <2.3	2.3 – <2.5	2.5 – <2.7	2.7 – <2.9	2.9 – <3.1	3.1 – <3.9	>4.0
Number in sample	21	22	30	29	29	22	24	25	25	22	20	21	21	20	21	20
Standard deviation (ml)	95.9	93.1	89.8	88.7	86.8	85.5	86.3	94.8	98.6	96.4	84.8	90.9	95.5	104.1	101.1	98.6
Coefficient of variation (%)	22.7	15.4	11.3	8.8	7.4	6.0	5.3	5.3	5.0	4.2	3.5	3.4	3.5	3.5	3.0	2.2
Significant changes in FEV_1 (ml)*	165.8	160.3	152.6	151.0	149.4	146.6	147.7	162.2	168.7	165.9	146.6	156.8	164.7	179.8	174.4	170.5

* The changes in FEV_1 required for 95% confidence in the change being due to reasons other than chance against the level of the FEV_1 where change is equal to tp × Standard deviation.

(tp = 95% confidence level of the t distribution for a given sample size using a one tailed analysis).

Results

The variability within each subgroup expressed as the mean of the individual coefficients of variation and the mean standard deviation against the level of FEV_1 is presented in Table 1.

One way analysis of variance showed that there was a highly significant difference in the coefficient of variation between the subgroups ($F = 41.3$: $p<0.001$), the coefficient of variation decreasing as the baseline FEV_1 increased. When the absolute variability, expressed as the standard deviation, was compared for the sixteen subgroups however, there was no significant difference between groups and no consistent trend towards larger absolute variability as the baseline increased.

The probability of a particular change in FEV_1 occurring by chance in a subject performing a forced vital capacity was calculated from the t-distribution and the sample standard deviation for each level of FEV_1. These results are presented in Table 1 at the 95% confidence level.

It can be seen from Table 1 that using the group with the largest variation, a minimum change of 180 ml is necessary to establish with 95% confidence that the given change is due to reasons other than chance. Taken as a percentage change this represents, for the subgroups of obstructed patients with the lowest FEV_1 and of normal subjects with the highest FEV_1, a change in FEV_1 of 45% and 4% respectively.

Discussion

There is continuing debate over whether an absolute or a percentage change should be used as the criterion for response to a bronchodilator drug and on whether different criteria should be used in normal subjects from those used in patients with varying respiratory disorders.

Thus Nickerson et al (1) showed that the variability within a set of FEV_1 measurements was different in normal subjects and in patients with cystic fibrosis and suggested that different criteria should be used for a significant change in these two groups, of 15% and 23% respectively. Cotes, (2) stated that the variability of FEV_1 within a set of measurements was independent of the size of the index but also suggested that a 10% increase in FEV_1 is a significant response to bronchodilator. Vale et al, (3) however, did not show any difference in variability of FEV_1 within a set of FEV_1 measurements in patients with different levels of FEV_1 and differing severity of airflow obstruction and suggested the use of an absolute change as the criterion for response but did not specify the level. Tweeddale et al, (4) also did not show any difference in the variability of FEV_1 when comparing normal subjects and patients with restrictive defects; nor did they find any difference in variability when differing levels of the FEV_1 were assessed. They specified an absolute change in FEV_1 of 190 ml as significant at the 95% confidence level. Tweeddale and McHardy (5) studied the short term variability in FEV_1 (over 20 minutes) in normal subjects and patients with obstructive and restrictive ventilatory defects. They found no significant difference in the variability of the FEV_1 between these groups, specifying a level of >175 ml as a significant change in FEV_1.

In the present study the variability between the highest and lowest measurements of FEV_1 in a set of three attempts was similar in normal subjects and in patients with airways obstruction, confirming earlier findings. The variability expressed in absolute terms was similar at all levels of a wide range of FEV_1. Significant changes can therefore be defined by a single absolute value, in this case 180 ml, that would be valid at any FEV_1 level but cannot be defined by a single percentage value. In practical use, given the confines of accuracy of the equipment used for measuring the FEV_1 the limit of a significant response to bronchodilator used would necessarily be 200 ml.

It must be remembered, however, that what may be a significant response statistically does not necessarily imply therapeutic benefit. On the other hand, what may well not be a significant response statistically, particularly in patients with a low FEV_1, (because it is within the range of natural variability for this group) does not imply no therapeutic benefit in a particular individual.

Bearing these factors in mind we now use absolute changes in the FEV_1 to define the response to bronchodilator drugs as part of a computerised interpretation programme. This programme uses a minimum level of 180 ml as a significant response to bronchodilator at all levels of the FEV_1. We have also included a statement for patients with low FEV_1 (<1 litre) who have an increase in FEV_1 after bronchodilator of 100 to 179 ml (Table 2).

Table 2

Statements and criteria for assessing the response to bronchodilator as used in a computerised interpretation programme for obstructed patients (FEV_1/FVC < normal range).

(A) "Bronchodilator produces no significant response."

Prebronchodilator FEV_1 < litre. Increment in FEV_1 after bronchodilator (inc FEV) < 0.1 litre
or
Pre FEV_1 > 1 litre inc FEV_1 < 0.18 litre.

(B) "Bronchodilator eliminates airways obstruction."

Post FEV_1 > lower limit of normal range
Post FEV_1/FVC ratio > lower limit of normal range
inc FEV_1 > 0.18 litre.

(C) "Bronchodilator produces a slight response."

0.36 litre > inc FEV_1 > 0.18 litre.

(D) "Bronchodilator produces a moderate response."

0.54 litre > inc FEV_1 > 0.36 litre.

(E) "Bronchodilator produces a good response."

inc FEV_1 > 0.54 litre.

(F) "Taking into account the low initial value of the FEV_1 the response to bronchodilator may indicate some therapeutic benefit."

FEV_1 < 1 litre
0.18 litre > inc FEV_1 > 0.1 litre.

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