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BREATH

CONTENTS

QUALITY CONTROL IN LUNG FUNCTION USING REPEATABILITY OF TESTS

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Summary

In this paper we review the subject of repeatability of the routine lung function tests FEV_1, FRC and TLCO and recommend its calculation as an element of quality control. We describe two indices:

1. The laboratory mean repeatability derived from the absolute differences between paired measurements (or, where appropriate, the percent absolute differences).

2. The coefficient of repeatability (7) derived from the actual differences and calculated as twice their standard deviation, thus encompassing 95% of observations. Tests such as FRC and TLCO are shown to require data transformation to percent differences in order to remove a positive correlation between the difference between pairs and the mean magnitude of the test. With FEV_1, no such correlation occurs (8, 9).

We describe the measurement and exclusion criteria of initial banks of 100 consecutive paired estimates of FEV_1, FRC and TLCO in our laboratory. Subsequently the results were updated by a simple moving average procedure and the indices of repeatability were charted against time. We found that the laboratory average repeatabilities for the first 100 pairs were: FEV_1 (asthma): 0.075 1.; FEV_1 (non-asthma): 0.04 1.; FRC: 3.7%: TLCO: 5%. Corresponding coefficients of repeatability were: FEV_1 (asthma): 0.16 1.; FEV_1 (non-asthma): 0.077 1.; FRC: 9.1%; TLCO: 11.7%.

Knowledge of our laboratory's current level of repeatability has focussed the attention of staff on the quality of work done and has helped with training. The clinicians have enjoyed an added dimension of confidence in test results where repeatability is depicted on a visual analogue scale. All this, we believe, justifies the extra work.

Introduction

Recent interest in the quality of work done in Pulmonary Function Laboratories has emphasised the need for adherance to correct and, if possible, standardised procedures especially in routine lung function tests (1-4). In these publications there is scant reference to quantification of components of quality such as repeatability or reproducibility of tests. Some publications quote either the coefficient of variation or the percent difference of duplicate tests without clear indications for the choice of statistic or the precise method of calculation. Tweeddale et al (8) have shown that percent change is inappropriate to estimates of difference in FEV_1 before and after bronchodilator. A similar conclusion was reached by Carter (9).

Bland and Altman (7) have described a statistical approach to estimating repeatability of duplicate tests using Peak Flow as illustration. They recommend the calculation of coefficient of repeatability from differences between duplicate readings. This coefficient is twice the standard deviation of the actual differences between estimates so that 95% of differences should lie below this limit. Their paper is mainly concerned with method comparison studies while our interest is in quality control. We feel that lung function laboratories would be helped by charting the repeatability of routine tests using the mean of absolute differences (or percent absolute differences where appropriate) between duplicates. The mean of absolute differences from, for example, 100 consecutive pairs of readings would provide an estimate of the current laboratory average repeatability of the test. This, together with the coefficient of repeatability as an outer limit, would provide a yardstick to compare with a) the repeatability of the test in an individual or b) the laboratory average repeatability of the test at different times or for different observers.

In a general sense laboratory quality control seeks to define the limits of variation in both accuracy and precision of tests so that deviations outside these limits can be identified and, usually, rejected. Lung function tests mainly use indirect methods of assessment and estimates of accuracy apply only to components of the test system such as gas analysers. Apart from calibration and checking for linearity there are no generally available methods of estimating accuracy in lung function. Two attempts to do this in Britain have been made (5, 6). The results were disappointing showing a disturbing frequency of inaccurate analysers with a deterioration in laboratory standards between 1962 and 1986 (6).

Precision measures the variation in repeated measurements and is divisible into reproducibility (which tests differences between batches or sessions) and repeatability (within batch or session). This paper describes the repeatability of measurements of FEV_1, FRC and TLCO for patients attending our lung function laboratory.

Methods

Apparatus: For FEV_1 a Vitalograph bellows spirometer was used. Volume was calibrated with a 1-litre precision syringe and time with a stop clock. Results were considered technically unsatisfactory if the expiratory curve was S shaped or interrupted by coughing or other artefact.

For FRC a Cardiokinetics non-automatic 'Volutest' closed-circuit helium dilution procedure was used. Daily calibration of the katharometer and leakage tests were performed. The katharometer was tested for linearity every week. A test was unsatisfactory if tidal breathing was persistently irregular or if there was evidence of leakage which was usually around the mouthpiece.

For TLCO a PK Morgan Transfer Test was used. The spirometer was calibrated with a 1-litre precision syringe and stop clock. Calibration of the infra-red analyser with air and known concentrations of carbon monoxide was done daily and its linearity tested monthly. Results were considered unsatisfactory if the patient was unable to inspire rapidly or to near TLC or had a forced vital capacity of less than 1.5 litres.

The three tests (FEV_1, FRC and TLCO) were performed in duplicate or triplicate on consecutive patients. If any test was technically unsatisfactory it was repeated after a pause. Rarely (less than 1% of cases) a pair of test results was excluded on technical grounds. We aimed to produce

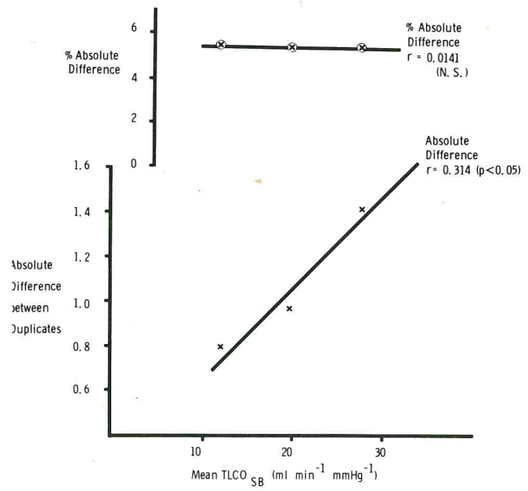

Fig. 1. *Relationship of absolute differences between duplicate determinations of TLCO and mean TLCO. Each point is the mean difference from 100 paired measurements in each of three groups representing contiguous ranges of magnitude. The correlation coefficient ceases to be significant when absolute differences are expressed as a percentage of the mean TLCO.*

banks of 100 paired results of each test. Because TLCO was already performed in duplicate we used the last 100 results in our day book. The same applied to FEV_1 which was done in triplicate from which we recorded the higher pair in the order of performance. FEV_1 results were divided into two groups, 'asthma' where there was evidence of obstructive pattern with at least 20% reversibility and 'non-asthma' with no obstructive pattern. The bank of 100 duplicate FRC results was collected prospectively because, hitherto, we had not routinely duplicated this test. Tests were performed by a series of technicians and students trained and supervised by one chief technician (M.A.S.)

When each bank of 100 pairs was complete we calculated the mean repeatability for each test as:—

1. mean percent absolute difference for TLCO and FRC.

2. mean absolute difference for FEV_1 both for 'asthma' and 'non-asthma'.

These means estimated the average level of repeatability of each test in our laboratory over the period of testing. In order to chart progress we used all patient's paired test results to re-calculate mean repeatability at intervals of 20 pairs which were added to the bottom of the existing 100, the top 20 being subtracted. These moving averages were then charted to enable trends to be visualised. We also charted for each test the coefficient of repeatability (see appendix for method of calculation). A computer program in M BASIC was written to facilitate the work of updating moving averages (copies from Mrs. M. A. Smyllie).

Results

Estimates of repeatability were derived from both the absolute and actual differences between paired tests. Mean repeatability was calculated from absolute, or percent absolute differences; coefficient of repeatability from actual differences. In the cases of TLCO and FRC the size of this

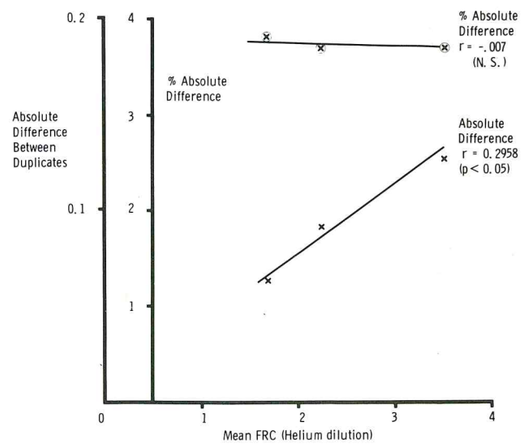

Fig. 2. *Relationship of absolute differences between duplicates and the magnitude of mean FRC. Each point is derived as in Fig 1.*

difference was positively correlated with the mean of the paired measurements but, when the difference was expressed as a percentage of the mean, the correlation was no longer significant (Figs 1 and 2). In the case of FEV_1 there was no correlation between the mean and the absolute difference between pairs so that here the difference itself can serve as the index of repeatability (Fig 3).

The means and coefficients of repeatability in our laboratory for FRC, TLCO and FEV_1 are illustrated in figs 4 to 7. These are charts of moving averages recorded over a period of approximately two years. For FRC (fig 4) the mean repeatability has remained stable near 3.7%. For TLCO (fig 5) the mean repeatability started at 5%, deteriorated towards 6% and then improved to 4.5%.

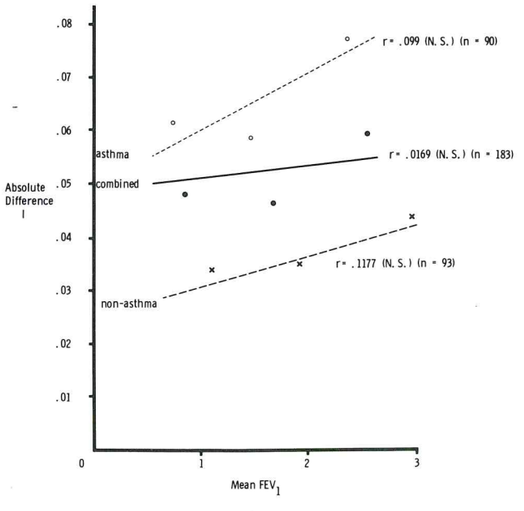

Fig. 3. *Relationship of absolute differences between duplicate determinations of FEV_1. Each point derived as in Fig 1. In brackets: number of patients in each group.*

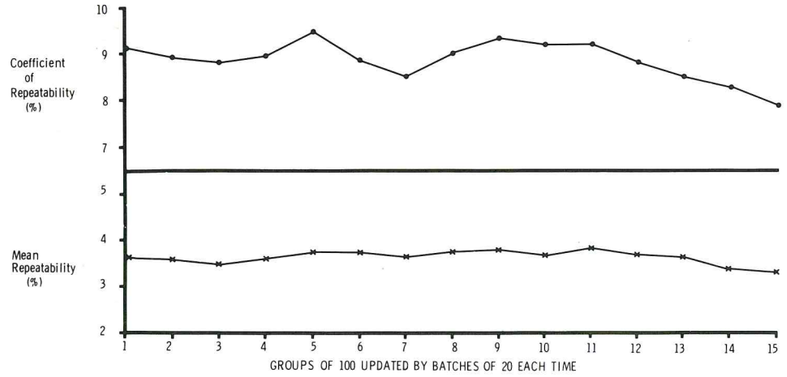

Fig. 4. *FRC: moving averages of mean and coefficient of repeatability based on percent differences.*

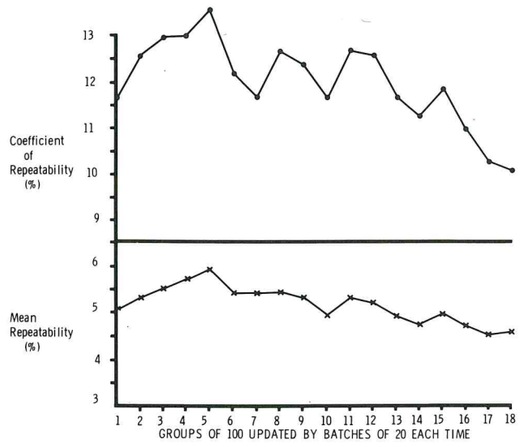

Fig. 5. *TLCO: otherwise as Fig 4.*

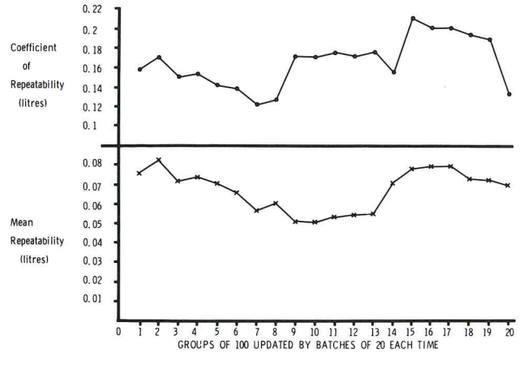

Fig. 7. *FEV_1 (asthma): otherwise as Fig 6.*

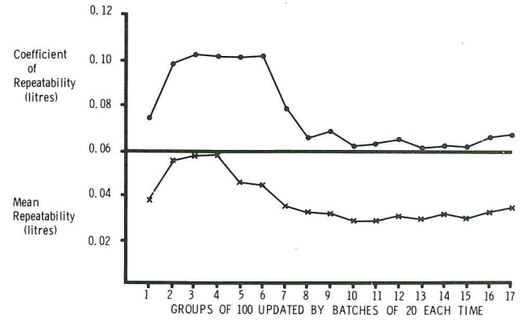

Fig. 6. *FEV_1 (non-asthma): moving averages based on absolute values.*

For FEV_1 ('non-asthma') (fig 6) the mean repeatability started at 0.04 1, initially deteriorated and then improved to 0.03 1. Mean repeatability for FEV_1 in asthmatics (fig 7) fluctuated a little around 0.075 1. Fluctuations in coefficients of repeatability tended to follow those of the moving averages.

Discussion

While adopting the coefficient of repeatability (7) as an acceptable limit to the repeatability of lung function tests we feel that it does not readily allow the comparison of a patient's test repeatability with the current laboratory average. Such a comparison we believe to be an essential part of the report to the clinician. Also, the coefficient runs the risk of focusing the attention of a trainee on a degree of repeatability that is just acceptable rather than desirable. For these reasons we have added the concept of average repeatability even though slight confusion may result from the fact that it is calculated from absolute differences (ignoring the sign) whereas for the coefficient, actual differences are required.

Tweeddale et al (8) and Carter (9) quote 190 and 180 ml respectively as the 95% confidence level for repeat FEV_1. Our coefficient of repeatability for asthmatics is 160 ml and for non-asthma, 77 ml, the method of calculation being somewhat similar. Direct comparison is probably not

appropriate because Tweeddale et al used the difference between the best of two sets of three FEV_1s, 20 minutes apart whereas Carter used the difference between highest and lowest of triplicates. We used the highest two of triplicate estimates. These differences reflect the different aims of the studies quoted.

Undoubtedly some extra work is required to run a quality control procedure such as we have described but not an excessive amount. Duplicate readings are current practice in the performance of TLCO; triplicates, for FEV_1; but FRC may not be duplicated in many laboratories. If not, an extra time allocation averaging 20 minutes will be needed for each test. Initial collection of 100 pairs of readings, recorded in order of performance for the relevant tests, and the calculations of repeatability involve a few hours' extra work. This burden, and that of updating with moving averages, is greatly lightened by access to a computer. Otherwise the calculations can be done with a statistical calculator and need approximately two hours per week.

We believe that the extra effort is worthwhile. Charting the laboratory's repeatability can give the staff a sense of pride of achievement and can record the progress of a trainee. The clinician gains extra relevant information from the technician's report thus assisting clinical decision-making.

Fig 8 illustrates the diagram we use for FRC and TLCO whose repeatabilities are derived from percent differences. On the scale, the patient's test repeatability is compared with the current laboratory average and coefficient of repeatability.

Repeatability depends on the effects of random variations in all parts of the test system such as the subject, the observer, the environment and the instrument (2). The use of moving averages irons out minor temporary fluctuations but should show trends in the laboratory's performance. We have sometimes found an explanation for upward deviation of our moving average indicating a reduction of precision. So far these have coincided with the induction of trainee technicians and improved with training.

Both clinicians and laboratory staff feel they have benefitted from the introduction of routine repeatability studies. Further work is needed to facilitate the comparison of tests repeated in the same patient after an interval, the reproducibility.

Acknowledgement

The secretarial help of Mrs. Jean Durdy is gratefully acknowledged.

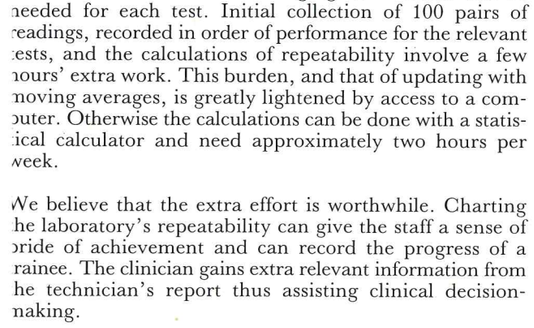

Fig. 8. Diagram used for FRC and TLCO. The repeatability in a given patient can be compared with the current laboratory data.

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Appendix

Calculation of coefficient of repeatability

1. FEV_1

Let x and y denote the first and second of any pair of measurements and let d be the difference between them. Assuming d is normally distributed and that the sample size is reasonably large, then an estimate of the range within which 95% of d values will lie is given by

$$D \pm 1.96\ Sd$$

where D and Sd are the sample mean and standard deviation of the differences d. If the ordering of the observations within a pair has no effect on the measurements then D will be close to zero and the probability that d is greater than (1.96 x Sd) will be approximately 0.05.

The coefficient of repeatability is defined as (1.96 x Sd) and this means that the absolute difference between a pair of readings will be less than this value in approximately 95% of instances.

2. FRC AND TLCO

For these variables, the difference d between a pair of estimates x and y is related to their magnitude. Then d can be transformed to d% which is given by

$$d\% = 100\ (x - y) \div \tfrac{1}{2}\ (x + y)$$

The standard deviation of d% can then be used to obtain the coefficient of repeatability as described above.

GAS MIXTURES FOR CO TRANSFER FACTOR — PRODUCTION AND QUALITY CONTROL

J. H. Scawin

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Measurement of the transfer factor for carbon monoxide (TLco) requires the use of a special gas mixture, usually containing carbon monoxide, helium, oxygen and nitrogen. As this mixture is breathed by humans, it is vital to prevent contamination and gas manufacturers and the suppliers must therefore take every precaution in the preparation and must ensure that the mixture conforms to the appropriate standards required for "Medical Quality" gases. This classification is distinct from "Industrial Quality" which may contain impurities harmful to humans. This paper briefly reviews the precautions and procedures needed to prepare the TLco mixture.

Cylinders

Material and Construction

The material from which the cylinders are constructed must be compatible with the gases they will ultimately contain. Since the TLco mixture contains CO, the use of steel cylinders for long-term storage is precluded since CO may either react with the steel producing metal carbonyls or be converted to carbon dioxide by the rust on the cylinder walls. Figure 1 shows the stability of a 0.28% CO in air mixture over a six month period.

With high nickel, chromium, iron cylinders a similar problem exists with the production of metal carbonyls. These carbonyls are highly toxic and should not be breathed. The maximum permitted occupational exposure limit is 0.05 ppm.

To avoid any deterioration in CO content, it is advisable to use a cylinder manufactured either in aluminium or aluminium alloy. This metal is a fairly low reactive material and does not produce toxic metal carbonyls with CO. The use and manufacture of cylinders is governed by BS 5045 (1) and BS 5604 (2). All gas cylinders are periodically inspected and tested according to BS 5430 (3).

Valve Outlets and Regulators

The choice of valve outlet is governed by BS 341 (4). Because of the nature of the gases, the BS4, ⅝ BSP left-hand screw must be used. The regulator control valve and flowmeter should be made of suitable materials and be compatible with the valve outlet.

Colour-Coding

To identify the contents of gas cylinders, all labels and stencilling should be read. As a secondary aid to hazard identification all gas cylinders should be colour-coded. This is in two forms. 1) Warning colour bands are placed at the valve end and may either be RED which indicates a flammable component and/or YELLOW indicating a toxic component. 2) The body of the cylinder is painted in a ground colour. Colours used for coding are defined in BS 349 (5) and BS 1319C (6). For the TLco mixture, CO is both toxic and flammable and will therefore have both a yellow and a red band. The ground colour will be pink (figure 2).

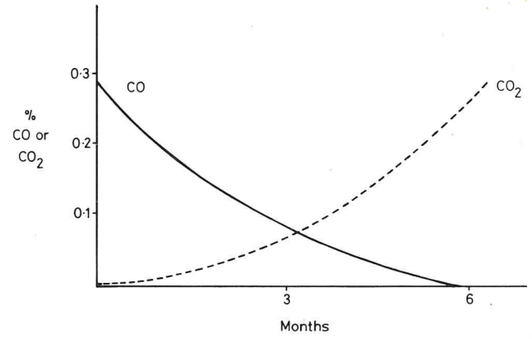

Fig. 1. Stability of 0.28% carbon monoxide in air over a 6-month period, when stored in a steel cylinder. The carbon monoxide decreases to approximately 0% whilst the carbon dioxide increases. Metal carbonyls may also be produced.

Production

Cross-contamination

All gas cylinders which are used in the production of medical gases are clearly labelled "Medical" or "Medical Use Only". Further potential cross-contamination is provided by evacuating all cylinders prior to filling. This removes any possible previous contamination that may have been in the cylinder.

Gases

All pure gases used in the preparation of mixtures are first tested for conformity to the European Pharmacopoeia (7). If a particular gas is not covered by this guide, then a higher specification is set by the gas manufacturers. In these cases, the manufacturers use their judgement to determine the

Fig. 2. Mixing and filling panel used to produce the TLco mixture. Note the clear labelling of the panel for medical mixtures, and the cylinder colour coding.

likelihood of a contaminant being produced in any particular process and ending up in that particular gas. No gas can be used for medical purposes unless it conforms to the required standards.

All base-line gases are tested for impurities using a dispersive infra-red spectrometer. Detection of impurities is down to sub-ppm levels.

Production and Certification

All cylinders are filled by trained personnel. They must ensure that all gases have been approved for use and that manifolds and filling panels are dedicated for the production of medical gases (figure 2). After each cylinder has been filled, the valve is date-stamped, thus allowing easy identification of when the mixture was prepared and of the batch to which it belongs.

Each gas mixture receives a certificate indicating that the contents conform to those requested by the customer. Prior to analysis, the contents of the cylinder are thoroughly mixed by rolling horizontally for at least 20 minutes.

The analysis of the contents is performed by a variety of recognised methods. Generally, gas chromatography or mass spectrometry is used. Both techniques are comparative: a sample is analysed and compared with a standard. The accuracy of the analysis is based therefore on the accuracy of the standard. These are usually prepared by gravimetric techniques, which are the most accurate. Certified weights are added to a highly sensitive balance and gases added in sequential order. The accuracy is estimated at better than ±1% relative.

Weighing procedures are carried out in an environmentally controlled laboratory where the humidity can be controlled to 55±5% relative humidity and at a temperature of 21°C±1°C. These controls remove errors caused by variations in temperature and humidity.

Following preparation by weight, each standard is verified, usually by comparison with a National Gas Standard. This allows each produced standard to be traced to a national body. The analyst will select the most appropriate standard for the analysis and calibrate the analyser after which the sample of the newly produced mixture can be analysed.

Production of the TLco mixture is carried out in an approved and dedicated laboratory system, which all technicians and analysts must follow. The analyst is unable to issue a certificate, until the supervisor has ensured and verified that the analysis has been completed correctly, that the proper equipment and standards have been used, and that the valve, labelling and stencilling are correct. Following certification, the final mixture may be re-inspected in a quality audit system implemented by Quality Assurance.

The final seal of approval is provided by an assessment carried out by a completely independant external body which reviews and inspects the procedures that are in operation for ''Medical Quality'' gas mixtures. Once the whole production process has been approved, the gas manufacturer can use the term ''Product Licence'' for its medical gas mixtures. This is the customer's guarantee of absolute safety.

Conclusion

The procedures that should be adopted by a gas manufacturer are complex and exhaustive, but are there to produce gas mixtures of the highest purity and quality for use with patients. By the very nature of the processes involved, the length of time for production is not short. However, this should not be allowed to cloud the issue of the necessity to use ''Medical Quality'' gases when patients are required to breath gas mixtures. A product licence is the customer's guarantee that the mixture conforms to the required level of quality, and when requesting any gas mixture for use on patients, it is important to state clearly that the mixture is to be of ''Medical Quality''.

References

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CORRESPONDENCE

Sleep Disordered Breathing and Screening Techniques

Martin Allen does us a valuable service in his article on ''Sleep Disordered Breathing and Screening Techniques'' (*Breath*, Vol. 32, November 1987, p.3) in presenting those features of which we should be aware in order to identify patients who should be referred for sleep studies.

He makes the valuable point that a sleep laboratory is expensive both to set up and to run, so this cannot be entered into lightly. Referral of screened patients to established centres is to be preferred, until the point is reached when those centres can no longer accept the increasing externally imposed work-load.

The allusion in the article to the fat boy, Joe, in Dickens's Pickwick Papers is interesting in context. Usually, this boy's condition (known perhaps erroneously as ''Pickwickianism'') has been associated with the opposite condition to that under discussion, i.e. instead of sleep disturbed by wakefulness it was wakefulness disturbed by sleep. Hypoventilation at rest when seated, induced by increased chest wall weight and the presence of the omental mass pressed up under the diaphragm in an obese subject, caused hypercapnia and hence low-grade CO_2 narcosis. This seems quite the opposite situation to the cause of sleep disturbance described in the article. Or perhaps they occured later, once the boy was asleep.

An important point about the flow-volume loop in upper airway obstruction is not brought out in the article. The ''flattened-off'' plateau seen in this condition is the fundamental feature. An abnormal FEF_{50}/FIF_{50} ratio is secondary, indicating the nature of the upper airway obstruction. The ratio without the plateau on the loop has no such significance. The reader is referred to the excellent review of this subject by Dr Empey in *Breath*, No. 15, February, 1982.

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Reply

I would like to thank Mr Peter Lockwood for his interest and comments about my article on ''Sleep disordered breathing and screening techniques'' (*Breath*, Vol. 32, Nov 1987, p.3). It is difficult to know whether Joe, the fat boy from Dickens's ''The Pickwick Papers'' suffered from sleep apnoea or just obesity. Certainly obesity is associated with changes in ventilation and ventilatory control, occasionally producing hypercapnia and hypoxaemia in morbidly obese individuals with subsequent daytime drowsiness (1). However many patients with the obesity/hypoventilation syndrome (first coined as ''Pickwickian'' in 1889 by Christopher Heath, President of the Clinical Society of London during the discussion of a paper and later as ''Pickwickian Syndrome'' by Burwell (2)), especially if they snore, actually have sleep apnoea (3).

With reference to the descriptions available of Joe, sleep apnoea would seem to be a more likely diagnosis than obesity alone, as suggested in the following extracts from ''The Pickwick Papers'':

— ''and on the box sat a fat and red-faced boy, in a state of somnolency''
— ''Joe — damn that boy, he's gone to sleep again''
In response to cannon fire — ''everybody was excited except the fat boy, and he slept as soundly as if the roaring of cannon were his ordinary lullaby''
— ''snores as he waits at the table''
— ''the fat boy rose, opened his eyes, swallowed a huge piece of pie he had been in the act of masticating when he last fell asleep''
Joe was called a — ''young dropsy''
— ''the fat boy's perception being slow''

These extracts illustrate the marked hypersomnolence, loud snoring and difficulty in arousing Joe, typical of sleep apnoea. The red face may refer to polycythaemia, the ''dropsy'' to concomitant heart failure and the slow perception to impairment in higher mental functions, again features of the sleep apnoea syndrome.

With respect to the appearance of the flow volume loop I felt that discussion of the characteristics seen in extrathoracic airway obstruction was beyond the remit of my article, especially having been recently reviewed. However, quoting the FEF50/FIF50 ratio does allow numerical comparisons between groups of patients to be made and in those referred for investigation elsewhere, the ratio may be a clue to their upper airway obstruction.

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SPRING SCIENTIFIC MEETING

The Spring Meeting of the Association took place on the 8th April 1989 at St Thomas' Hospital, London. We owe grateful thanks to Patricia Tweeddale and Jennifer Cuneo for organising the meeting, to the speakers for their excellent papers and to the following firms who generously sponsored the meeting and exhibited their products.

Pall Biomedical
Puritan Bennett
Henley's Medical Supplies
Micro Medical
S & W Vickers
BOC Special Gases
Medic-Aid Limited
Erich Jaeger UK
PK Morgan
Vitalograph

Scientific Papers

Comparison of a single breath and a multiple breath method of measuring the total lung capacity. P Lockwood and MH Lloyd.

Treatment of interstitial lung disease. J Wiggins.

Asthma — where do we go from here? M Partridge.

Increased exercise tolerance with 0_2 therapy in chronic airways obstruction. R Leach.

Contamination and its control in pulmonary function laboratories. G Lloyd.

Development of a respiratory function service for HIV positive patients at St Mary's Hospital. E Billing.

Particular problems for the respiratory laboratory relating to intravenous drug misusers. PM Tweeddale.

Sally Gough Book Prize

Congratulations to Carl Fitter who was awarded the prize as the best candidate in the National Assessment for 1988.

Report on Carbon Monoxide Gas Transfer Course held on 9th March, 1989

The Carbon Monoxide Gas Transfer Course held on 9th March, 1989 at the Derbyshire Royal Infirmary was a great success. There was an excellent response to this Course and 35 people attended.

Mr Adrian Kendrick who is a Research Assistant at Bristol Royal Infirmary was an interesting and informative speaker covering such areas as the history and development of gas transfer, calculations and techniques, and calibration and quality control of analysers. A lively general discussion followed. Our thanks go to Mr Kendrick for the tremendous amount of time and effort involved in preparing this full day seminar.

Thanks also to PK Morgan who lent the Gas Transfer Single Breath equipment used as a demonstration model.

Everyone present enjoyed the lunch provided in the Chatsworth Suite of the Derbyshire Royal Infirmary.

All in all, this was a most enjoyable day and it is hoped that further courses such as this may be arranged in the future.

Mrs V Hurt
Secretary to the Association
of Respiratory Technicians
and Physiologists.

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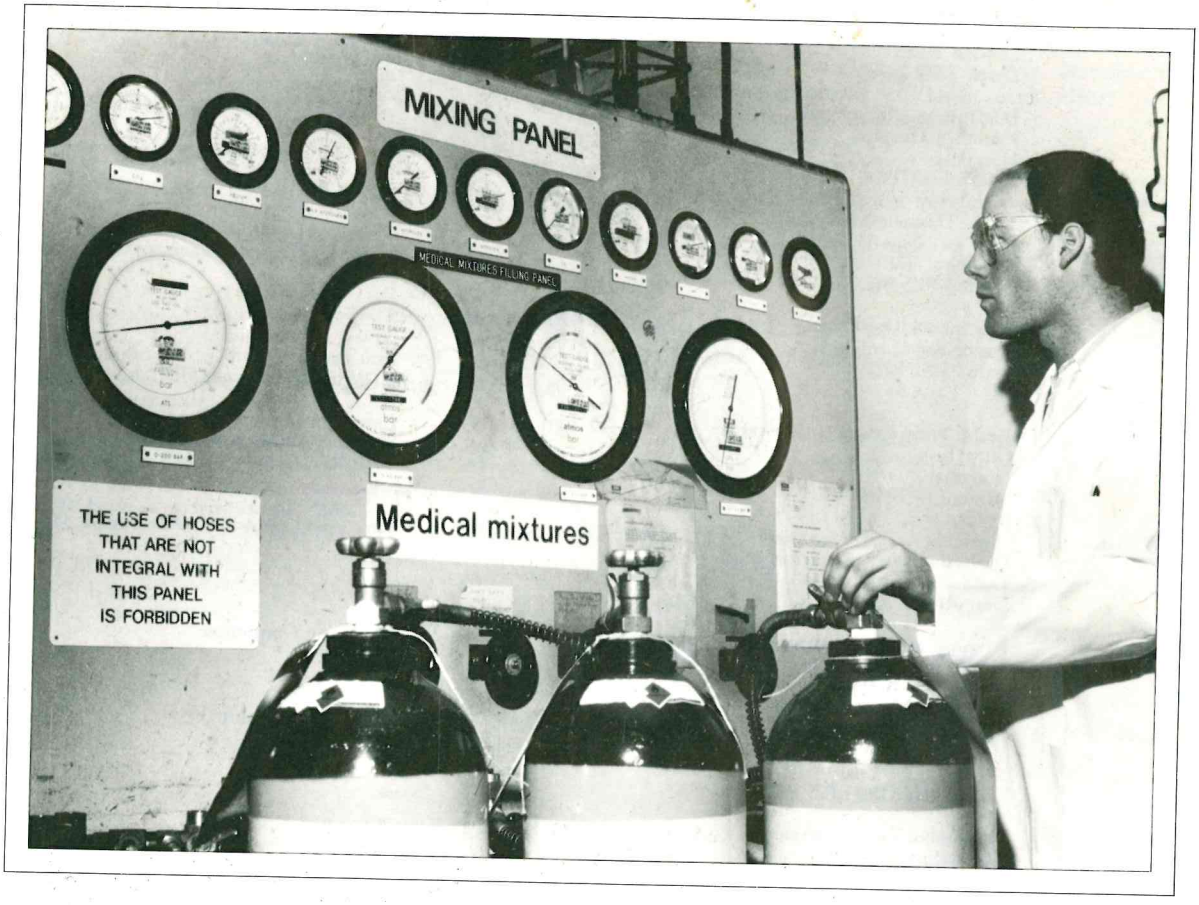

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