Training in Multiple Breath Washout testing for respiratory physiotherapists

Debate article

Title: Training in Multiple Breath Washout testing for respiratory physiotherapists

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Title: Training in Multiple Breath Washout testing for respiratory physiotherapists

Abstract: 146/200

Introduction: The development of multiple breath washout (MBW) testing in respiratory disease highlights the need for increased awareness amongst respiratory physiotherapists and a potential opportunity for professional development in the use of an important outcome measure for clinical trials.

Objectives: To rationalise how MBW may be a useful assessment tool for respiratory physiotherapists and to describe a local MBW training and certification programme for physiotherapists.

Results: The respiratory Multi-Disciplinary Team in the Belfast Health and Social Care Trust (BHSCT) identified a need for MBW testing to be available to facilitate clinical research and assessment. A 2 day training programme consisting of pre-reading preparation, self-directed learning, theory presentations, practical demonstrations and hands-on practice was developed and delivered. All participants underwent a certification process.

Conclusion: We have demonstrated the successful training and certification of clinical and research physiotherapists and encourage other respiratory physiotherapists to consider MBW test training.

Contribution of paper

- This paper highlights the need for increased awareness amongst respiratory physiotherapists and a potential opportunity for professional development in the use of an important outcome measure for clinical trials.
- This paper demonstrates that respiratory physiotherapists can obtain training and certification in MBW testing

Keywords

Respiratory physiotherapy; multiple breath washout testing; lung clearance index; training; eLearning.

Introduction

In recent years, there has been a resurgence of interest in multiple breath washout (MBW) testing in respiratory disease. This method has the advantage of improved sensitivity in the detection of early airways disease compared to spirometry and has improved feasibility across a wider age range, requiring only relaxed tidal breathing. Studies in Cystic Fibrosis (CF) have shown that measures of MBW detect early lung disease, relate to measures of spirometry and health related quality of life and are responsive to mucolytic therapies (1-7). Consequently, parameters of MBW have been recommended as outcome measures in clinical trials in CF (8) and have already been used in landmark CF trials (9,10). Research into MBW in other respiratory conditions have also demonstrated that it could be a useful tool to detect disease and measure treatment response (11-14). FEV_1 is a key outcome measure in CF and is currently the only Food and Drug Administration (FDA) approved surrogate outcome measure for use in clinical trials (15). It is also the most commonly used and reported measure of lung function in other lung diseases such as COPD (16). However, FEV_1 has physiological limitations; it primarily reflects the larger airways rather than the more peripheral, smaller airways which make up the majority of the surface area of the lung and where early processes occur (17). Furthermore in CF, the slow rate of decline in FEV_1 evident as a result of improved standards of care (18), limit its sensitivity to detect change in clinical status and response to treatment. Spirometry can only be reliably carried out in individuals aged >6 years as it requires ability to take instruction and co-operation. There is a clear need for an alternative measurement of lung function. As research has established that MBW is a valid and reliable measure of ventilation distribution which correlates with lung disease severity (8), it has become established as a secondary outcome in clinical trials and may also have a place in regular clinical monitoring in CF. Moreover, MBW could potentially inform physiotherapy assessment and the evaluation of new treatments.

Unlike spirometry, MBW is not part of undergraduate training programmes and there are few training programmes outside specialist research centers. Therefore, in order to facilitate the translation of MBW into clinical care there is a need for effective training. We propose that training respiratory physiotherapists to perform MBW could be advantageous in the management of respiratory patients.

Objectives

The objectives of this article are to

1. Rationalise how MBW may be a useful assessment tool for respiratory physiotherapists.

2. Describe a local MBW training and certification programme for physiotherapists.
3. Highlight available MBW training resources.

MBW testing

In respiratory disease, airway narrowing from mucus obstruction, inflammation and structural airway damage can cause uneven ventilation distribution and the degree of disease severity can be assessed using MBW. Lung Clearance Index (LCI) is the most commonly reported measure of the MBW test and represents the number of functional residual capacity (FRC) volume turnovers required to “washout” the tracer gas during testing. Individuals with uneven ventilation distribution use a greater number of turnovers to washout the tracer gas and therefore will have a higher (more abnormal) LCI. Although MBW tests have been available for many years, research and clinical interest has increased recently due to the availability of more sophisticated and user friendly equipment. The MBW test can be performed either with inhalation of an inert tracer gas such as sulphur hexafluoride (SF_6) or helium (He), or by using 100% oxygen (0_2) to wash out resident nitrogen (N_2). When using SF_6 or He, the gas is first washed into the lungs and then washed out. When using N_2 washout, 100% 0_2 is delivered until N_2 is washed out. The European Respiratory Society/American Thoracic Society (ERS/ATS) consensus statement for inert gas washout measurements (19) provides evidence based guidelines on equipment specifications, test performance and analysis of results and is a key reference document for sites planning the set-up and delivery of MBW testing. Some key points about MBW from the inert gas washout measurements consensus statement (19) and an evidence review for LCI (8) are summarized in Table 1.

Table 1: MBW key points

• MBW tests assess the efficiency of ventilation distribution (19) • LCI is the most commonly reported MBW index in current paediatric and adult literature (19) • LCI is the number of functional residual capacity (FRC) lung volume turnovers required to reduce tracer gas concentration to a fraction of its starting concentration (19) • End of washout is historically defined as 1/40th of the starting tracer gas concentration (19) • MBW testing requires only tidal breathing and stability of resting lung volumes throughout the washout is critical (19) • LCI is reported as the mean (SD) of 3 technically acceptable and repeatable washout tests (19) • In a healthy person, upper limits of normal for LCI between 7.0 – 7.5 have been reported (2,30) • A complete MBW testing session (3 tests) typically lasts between 20 - 40 minutes (2,31) • The minimum clinically important difference in LCI has yet to be defined but treatment effects of 1.0-2.2 lung turnovers have been reported (3,9,32,33) • LCI is dependent on body size and appropriate reference equations are essential for accurate interpretation of results (34) • Results are specific to equipment and therefore are not comparable across different systems (e.g. system using SF_6 vs. system using N_2 as tracer gas)

There are key areas where LCI demonstrates potential clinical utility. Firstly, LCI can detect early lung disease, potentially informing clinical decisions on treatment and management plans earlier in the disease trajectory. It has been shown to detect early lung disease in children and adults and is more sensitive than measures of spirometry (FEV_1) in both CF and bronchiectasis (2,5,11). Indices from the MBW test have also been shown to be sensitive to lung disease in asthma (13), COPD (14) and alpha-1-antitrypsin deficiency (20).

Importantly, LCI relates to other meaningful clinical endpoints and patient centered outcomes, which confirms its validity as a useful measure. In CF, LCI has been shown to relate to health related quality of life as measured by a validated questionnaire, and to predict pulmonary exacerbations (4,21). In both CF and bronchiectasis, LCI relates to measures of high resolution computed tomography (HRCT) chest imaging (11). LCI has been shown to be responsive to the disease modulating therapy, ivacaftor, in CF (9). LCI, but not FEV_1% predicted, was also responsive to mucoactive therapies including inhaled hypertonic saline (3) and DNase in CF (7). The responsiveness of LCI highlights that it could have a potential role in the assessment of therapies and in the long term monitoring in patients.

A small number of studies have been carried out to investigate the short term effect of airways clearance interventions on LCI in both CF and bronchiectasis. In CF, one study demonstrated a significant reduction (improvement) in LCI following treatment with Non-Invasive Ventilation compared to Positive Expiratory Pressure mask in 32 patients with CF (22). Measures of gas mixing efficiency from a single-breath gas washout test also improved significantly after airway clearance in 25 children with CF (23). The majority of studies show no change or a variable change (increase and decrease) in LCI (12,24-26). This highlights that airways clearance techniques cause alterations in gas mixing which are greater than those who do not undergo airway clearance. One theory suggested is that airway clearance may open up previously “blocked off” areas caused by mucus plugging, or relieve areas of atelectasis, opening up poorly ventilated areas, thereby causing a rise (worsening) in LCI. Further studies of the medium to long-term effect of airways clearance techniques on LCI and other MBW test outcomes would be beneficial in informing physiotherapists whether there is a place for MBW testing in assessing airways clearance. The challenge with airways clearance trials remains that there is no consensus on the best index to use to measure effect (27).

As MBW testing demonstrates utility across a range of respiratory diseases, both clinical and clinical trial sites are exploring the acquisition of equipment and training in order to embed this outcome measure in trials and to offer this test as part of their assessment. This highlights a development opportunity for respiratory physiotherapists.

The role of respiratory physiotherapists

Respiratory physiotherapists are directly involved in conducting and interpreting lung function tests and the key role of the physiotherapist in evaluating response to inhaled therapies, airways clearance therapies and physical activity has been highlighted in CF (28). Physiotherapists are ideally placed to build on their existing knowledge and expertise in acquiring the skill of MBW testing, which could potentially be utilized as part of their patient's assessment. Respiratory physiotherapists form an integral part of the multidisciplinary team and are involved in the assessment of patients' respiratory status within the context of outpatient appointments, annual assessments as well as inpatient admissions. MBW testing falls under the Chartered Society of Physiotherapy (CSP) scope of practice of physiotherapy in the UK, defined as "any activity undertaken by an individual physiotherapist that may be situated within the four pillars of physiotherapy practice where the individual is educated, trained and competent to perform that activity" (CSP, 2008) and therefore is covered under professional liability insurance. As MBW testing has its roots in clinical research, conduct of the technique has historically been the remit of the researcher. Implementing research practices into clinical practice is challenging and requires the collaboration and commitment of the academic researchers, clinicians, managers and patients. Increasing awareness and knowledge of new assessments, skills required and the wider practical implications are recognised aspects of successful integration of change to practice (29). A key feature of all clinical practice including physiotherapy practice, is the capacity to respond and evolve to changes in healthcare. A focus on providing the training opportunities to support physiotherapists to be competent at embedding new techniques within their clinical practice will facilitate the translation of research into practice. To enable the successful integration into clinical practice, appropriate training in the technical aspects of set up, conducting the test, and interpretation and quality assurance of results is essential (19). Through our experience of delivering a training programme, we have demonstrated how both clinical and research physiotherapists can successfully complete training and certification in this skill for use in research and clinical practice.

Training programme

The respiratory Multi-Disciplinary Team in Belfast Health and Social Care Trust (BHSCT) identified a need for MBW testing to be available to facilitate clinical research and clinical assessment. In response to this, a 2 day programme was developed and delivered by a Queen’s University Belfast PhD researcher (physiotherapist KON) trained in using the modified Innocor™ device (by an external expert in the equipment, Dr Alex Horsley, University of Manchester). The programme consisted of pre-reading preparation, self-directed learning, a presentation on theory, practical demonstrations and practice. Thereafter to be certified, participants completed 10 tests after the 2 day programme which were then assessed for technical validity and repeatability. The trainer was available for trouble shooting on calibration and testing during the certification process. Table 2 details the programme content and layout and the certification procedure. Appendix 1 details the programme in full. All content was based on the device Standard Operators Procedure (used with permission) “Multiple breath washout test using modified Innocor^{TM} device SOP; UK Cystic Fibrosis Gene Therapy Consortium; September 2010, Dr. Nick Bell” and on guidance from external expert Dr Alex Horsley, University of Manchester. A knowledge (6 multiple choice questions) and confidence (Likert visual analogue scales rating setting up the equipment, conducting and interpreting the test) questionnaire was completed by participants before the programme and after submission of certification tests (appendix 2). Participants were also asked to make suggestions for improvement of the programme.

Table 2: Programme content and layout

Preparation: Key references and protocols for pre-reading.
Day 1: Background to MBW. Overview of references and Standard Operating Procedure. Familiarisation with equipment components, on-screen menus and consumables. Overview and practice of calibrations. Patient preparation for testing.
Day 2: Explanation and demonstration of phases of testing: Washin phase, beginning of washout, washout phase. Practice testing with volunteer and quality control of readings. Log keeping, cleaning of equipment and infection control. Accessing and downloading tests.
Certification procedure:

Trouble shooting on calibration and testing.

Collection of 10 tests.

9/10 technically acceptable tests required for certification.

If <9/10 tests valid, submission of additional 5 tests.

The programme was delivered on 2 occasions to a total of 10 participants (5 clinical researchers [3 physiotherapists, 1 nurse, 1 clinical physiologist] and 5 clinical physiotherapists) based in BHSCT. All 10 participants completed the 2 day programme. However 2/10 participants (clinical physiotherapists) did not complete the certification procedure (no time due to clinical caseload). The remaining 8 participants successfully completed the certification procedure. Six participants completed the knowledge and confidence assessment before and after the programme and certification (2 participants did not complete the certification and 2 completed the programme before the knowledge and confidence questionnaire was introduced). For these 6 participants, knowledge improved from 61% at baseline to 100% post programme. Confidence improved from 3% at baseline to 76% post programme; however 2 participants highlighted that they still were not very confident in interpreting MBW results. Suggestions for improvement included the development of eLearning material, the inclusion of content on N_2 washout devices and information on the interpretation and analysis of MBW results.

Experience from this programme demonstrates how both clinical and research physiotherapists can successfully complete a training and certification programme in MBW testing. As 2 clinical staff members were unable to complete certification due to time constraints it highlights that agreement and ongoing support from management is required to ring fence time to organise and complete certification readings.

Resources for MBW training

For those wishing to pursue training in MBW testing, the ERS/ATS inert gas washout consensus statement provides a comprehensive outline on all aspects of equipment specifications, test performance and analysis (19). As MBW testing involves practical and technical skills, face-to-face training for "hands-on" experience is considered optimal. During the equipment installation process manufacturers usually provide training according to their standard operating procedure. Additional training is required to obtain certification to a research quality standard and there are UK sites who provide training, certification and an over-reading service (quality checking and final result verification of MBW data) as well as a point of contact for re-fresher training and troubleshooting. (Royal Brompton and Harefield Hospital, London and BHSCT).

MBW testing is a developing area and is technically challenging to perform. Therefore, regular practice with quality control checks is essential to ensure that confidence and competence with use of the equipment is maintained. Re-fresher training is important if time has elapsed since original training or last use. As MBW is primarily a research tool at present, it is possible that the operator may become deskilled if using the method infrequently or only during a specific clinical trial. eLearning tools are one method that reinforce face-to-face learning and support re-fresher training remotely. Some eLearning resources have been developed by commercial companies using MBW testing, however access is restricted to sites participating in the clinical trial. An eLearning tool developed at Queen's University Belfast (www.MBWtraining.com), is open access and provides comprehensive information on MBW testing using a variety of learning mediums including slideshow presentations, animations and a step by step library of videos demonstrating set-up and testing. The tool also includes a selfassessment component, a social networking interface and teaching team contact details for on-going support. In addition to reinforcement of face-to-face learning, this eLearning tool aims to facilitate ongoing and re-fresher training and act as a point of contact for troubleshooting and quality assurance issues. This blended learning approach (face-to-face programme supported by eLearning) aims to provide an effective and accessible form of MBW training to sites.

Conclusions

MBW to measure LCI is emerging as a promising outcome measure with potential for integration into routine clinical management of patients with CF and growing potential for use in bronchiectasis, asthma and COPD. In order for integration into clinical practice to be successful, training of the appropriate personnel in the technical aspects of set up, conducting the test, interpretation and quality assurance of results is essential. We propose that respiratory physiotherapists are ideally placed to undergo such training and become qualified to perform the MBW technique in response to expansions in service delivery. We have demonstrated the successful training and certification of clinical and research physiotherapists and encourage other respiratory physiotherapists to explore the area of MBW test training.

Ethical approval: n/a

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Conflict of interest: The authors have no conflicts of interest to disclose.

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Appendix 1: Training Programme: Multiple Breath Washout Test using Modified Innocor^{TM} device: Queen's University Belfast & Belfast Health and Social Care Trust

PROGRAMME

Multiple Breath Washout (MBW) Test using Modified Innocor^{TM} device: Queen's University Belfast & Belfast Health and Social Care Trust

Author: **Katherine O'Neill, Prof. Judy Bradley, Prof. Stuart Elborn.**

INSTRUCTIONAL GOALS

At the end of this course, you will:

- Understand the principals underpinning MBW testing.
- Be able to independently prepare the InnocorTM device and the testing room for procedure.
- Be able to independently set up device and perform all calibration procedures as per SOP
- Be able to maintain the set up to standard as per infection control guidelines in the SOP.
- Know how to complete and maintain the Innocor^{TM} Usage log and the MBW Procedure and Analysis Washout Sheets.
- Know how to adequately explain and prepare patient for procedure.
- Be able to successfully conduct MBW test on adults as per SOP.
- Be able to recognize technically inadequate tests that may warrant an additional test.
- Be able to export the test tracings from the Innocor^{TM} device in preparation for analysis.

NEEDS AND RESOURCES

Required Background

To successfully complete this course, you must;

- Read the key references

➢ Robinson, P.D., Goldman, M.D. & Gustafsson, P.M. 2009, "Inert gas washout: theoretical background and clinical utility in respiratory disease", *Respiration*, vol. 78, no. 3, pp. 339-355.

➢ Horsley, A. 2009, "Lung clearance index in the assessment of airways disease", *Respiratory medicine,* vol. 103, no. 6, pp. 793-799

- Read the SOP

➢ Multiple breath washout test using modified InnocorTM device SOP; Nick Bell; Clinical Research Fellow; UK Cystic Fibrosis Gene Therapy Consortium; 20th September 2010.

Required Equipment

To commence and successfully complete this course, you will need

- Innocor^{TM} in place with adaptations made as per SOP (see page appendix C SOP)
- Supply of SF6 gas (NB: Wall bracket or cylinder trolley for size L cylinder required; flow head/regulator for size L cylinder required (ordered through BOC part number 850820) (see page 5 SOP)

- Room set up for procedure (see page 5 SOP)
- Flow past circuit and patient interface consumables in stock (see page 19 SOP)

Required Materials

To successfully complete this course, you will need;

- Multiple breath washout test using modified Innocor^{TM} device SOP; Nick Bell; Clinical Research Fellow; UK Cystic Fibrosis Gene Therapy Consortium; 20th September 2010.
- MBW Procedure and Analysis Washout Sheets
- Multiple Breath Washout Test using the Modified Innocor^{TM} device ; LCI operator Qualification Assessment Form; Oct 2011
- Innocor^{TM} Instructions for Use Manual

COURSE CONTENT

TRAINING ITEMS
1. Overview of references and SOP. 2. Checklist of all equipment and consumables in place 3. Set up room, equipment and patient interface 4. Familiarisation with equipment a) Innocor™ b) Innocor™ menus c) Patient interface d) Flow past circuit e) Gas cylinder f) Room set up 5. Practice with set up and calibration a) Flow meter linearization b) Flow meter calibration c) Flow gas delay calibration 6. Preparing and explaining procedure to patients 7. Concepts of washin; disconnection and washout (as per SOP). 8. Observe a test *Volunteer needed* 9. Supervised practice with patients / volunteers *Volunteer(s) needed*

a) Including keeping the log and note keeping during the test.

b) Troubleshooting: Awareness of reasons for invalid tests (technician related and patient related) and how to avoid.

10. Infection control procedures

a) Patient interface

b) Room

11. Accessing and downloading tracings; sending tracings to analyzer.

12. Information obtained post analysis.

Certification procedure (completed independent post programme)

Trouble shooting on calibration and testing.

Collection of 10 tests.

9/10 technically acceptable tests required for certification.

If <9/10 tests valid, submission of additional 5 tests

Appendix 2: Knowledge and Confidence Assessment Questionnaire_ Multiple Breath Washout Test using Modified Innocor^{TM} device_Queen's University Belfast & Belfast Health and Social Care Trust_Katherine O'Neill_March 2013

Knowledge assessment questionnaire

Multiple choice questions- Please choose one

1. LCI is derived from

a) Single breath washout test

b) Multiple breath washout test

c) Body plethysmography test

d) Diffusion capacity test

2. LCI is a measure of

a) Airflow

b) Perfusion

c) Inflammation

d) Gas mixing efficiency

3. The upper limit of normal for LCI is

a) 10

b) 5.5

c) 7.5

d) 15.5

4. LCI is calculated as

a) The number of lung turnovers required to washout a tracer gas

b) The concentration of tracer gas at functional residual capacity

c) The mean concentration of $C0_2$ at end tidal volume

d) The number of lung regions ventilated

5. LCI is a measure most sensitive to

a) Large airways dysfunction

b) Small airways dysfunction

c) $Sp0_2$ levels

d) Airways inflammation

6. LCI is a measure which is most informative in

a) Patients with advanced disease

b) Patients awaiting transplant

c) Healthy individuals

d) Children and patients with mild disease

<u>Confidence assessment questionnaire</u>

Please answer the following questions which relate to your confidence in MBW procedure to obtain LCI

Rate your confidence performing **calibration procedures for MBW testing** before starting the training programme

Not confident 0 1 2 3 4 5 6 7 8 9 10 Very confident

Rate your confidence performing **calibration procedures for MBW testing** on completion of the training programme

Not confident 0 1 2 3 4 5 6 7 8 9 10 Very confident

Rate your confidence using **<u>equipment to perform MBW test</u>** before starting the training programme

Not confident 0 1 2 3 4 5 6 7 8 9 10 Very confident

Rate your confidence using **<u>equipment to perform MBW test</u>** on completion of the training programme

Not confident 0 1 2 3 4 5 6 7 8 9 10 Very confident

Rate your confidence on **<u>interpreting the LCI result from the results sheet</u>** before starting the training programme

Not confident 0 1 2 3 4 5 6 7 8 9 10 Very confident

Rate your confidence **interpreting the LCI result from the results sheet** on completion of the training programme

Not confident 0 1 2 3 4 5 6 7 8 9 10 Very confident

Rate your confidence on **maintenance of the MBW equipment** before starting the training programme

Not confident 0 1 2 3 4 5 6 7 8 9 10 Very confident

Rate your confidence **maintenance of the MBW equipment** on completion of the training programme

Not confident 0 1 2 3 4 5 6 7 8 9 10 Very confident