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Abstract

Respiratory physiotherapy is part of the routine management of patients with cystic fibrosis. It normally consists of airway clearance techniques and exercise training. The evidence of such interventions has been questioned. Nevertheless, the lack of evidence should not be interpreted as lack of benefit. Instead, attention to methodological issues, such as the selection of the outcome measures, is needed, as they may hamper the establishment of the effectiveness of respiratory physiotherapy techniques. Hence, this chapter presents and discusses the strengths and weaknesses of conventional and emerging outcome measures possibly to be used (i) in clinical practice before, during and after each session of respiratory physiotherapy to monitor its effectiveness; (ii) before and after the respiratory physiotherapy treatment (i.e., normally characterised by weeks of intervention) and (iii) in applied research in respiratory physiotherapy used in the management for cystic fibrosis. A comprehensive overview of the available outcome measures is provided, with particular emphasis on their strengths and limitations that should be recognised when interpreting the results.

Keywords: Respiratory physiotherapy, outcome measures, cystic fibrosis

1. Introduction

Respiratory physiotherapy is a non-pharmacological treatment commonly provided to patients with cystic fibrosis (CF) [1]. According to international guidelines, respiratory
physiotherapy is a key element of care for patients with CF, as it aims at both rehabilitation and prevention [2]. Specifically, respiratory physiotherapy is used to deal with the progressive loss of pulmonary function accompanied by symptoms of cough, excessive sputum production, dyspnoea, exercise intolerance, reduced functionality and impaired quality of life. To respond to these multiple problems and needs, respiratory physiotherapy involves a range of strategies and techniques, such as airway clearance, exercise training and breathlessness management, which have an overall aim of reducing the progression of the disease [3, 4].

However, there is a lack of evidence to suggest the superiority of one technique over the other [5] and to determine which strategies promote the adherence of this population to regular physical activity [6]. Nevertheless, the lack of evidence does not mean lack of benefit. Instead, methodological issues, such as the selection of the outcome measures, may hamper the establishment of the effectiveness of the respiratory physiotherapy techniques.

Respiratory physiotherapists use several outcome measures to monitor and evaluate their interventions. Most of the clinically available outcome measures are not specific for the physiotherapy intervention employed and may be affected by other factors. This means that there are no gold standard outcome measures specifically related to respiratory physiotherapy interventions. Thus, in all areas of respiratory physiotherapy, one of the barriers to generate evidence has been the lack of accurate, reliable, sensitive and valid outcome measures. To overcome this problematic issue, new measures have been emerging.

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This chapter starts by providing an overview of the problem. It then presents and discusses the strengths and weaknesses of the commonly used clinical outcome measures and other measures that have been gaining interest in the assessment and monitoring of respiratory physiotherapy interventions in CF. The chapter ends with a brief conclusion. A comprehensive overview of the available outcome measures is sought to be provided, with particular emphasis on their strengths and limitations that should be recognised when interpreting the results.

2. Outcome measures for respiratory physiotherapy

Respiratory physiotherapy in CF involves a wide range of interventions and among them airway clearance techniques and exercise training are recognised as the most important. The primary aim of airway clearance techniques is to relieve the airway obstruction by promoting the normal mucociliary clearance mechanism of the lungs and facilitating expectoration, thus reducing the risk of infection and inflammation. A variety of airway clearance techniques have been developed. Some involve airway oscillation, some are independently performed and others require electricity or physical assistance [5]. Exercise training is advocated as an important package of care delivered to patients with CF [5], since exercise intolerance has been associated with reduced survival [45]. Observed benefits of exercise training include slow pulmonary function decline [46], reduced dyspnoea and improved exercise capacity, muscle strength and health-related quality of life (HRQoL) [47].

Although adhering to airway clearance techniques [7] and exercise training is generally regarded as beneficial for patients with CF, there is no consensus about the superiority of one
technique over the other [5]. Methodological issues, such as the underpowered samples or the selection of the outcome measures, may explain this lack of evidence and thus hamper the establishment of the effectiveness of these interventions. A clear example of this issue has been the use of forced expiratory volume in the first second (FEV₁) as a gold standard to assess the impact of the mentioned interventions for many years, which is currently considered as not a sensitive measure to be used in respiratory physiotherapy [5].

Most of the clinically available outcome measures are not specifically related to the physiotherapy intervention employed and may be affected by other factors. This means that there is no gold standard outcome measure that is specifically related to respiratory physiotherapy interventions. Moreover, there are many doubts about the accuracy, reliability, sensitivity and validity of the current measures. Given this problematic situation, several researchers have been investigating the potential of other objective, simple and non-invasive measures to be used as outcome measures in respiratory physiotherapy.

The outcome measures most commonly used by respiratory physiotherapists to monitor their interventions and evaluate their practice are: FEV₁, respiratory sounds, sputum weight, measures of oxygenation, chest radiography, dyspnoea, exercise capacity and HRQoL. Computerised respiratory sounds, lung ultrasound, fat-free mass, inspiratory muscle strength and endurance, physical activity and burden of treatment are some examples of these emerging outcome measures to assess and monitor respiratory physiotherapy interventions in CF. Each one of these outcome measures, their strengths and weaknesses are presented in detail below according to their novelty in the field (i.e., conventional and emerging).

2.1. Conventional outcome measures

2.1.1. Forced expiratory volume in the first second

The most common pulmonary function test performed to assess respiratory physiotherapy interventions is the forced spirometry, i.e., the volume and/or flow of air that can be inhaled and exhaled as a function of time. The procedure consists in three distinct phases: (1) maximal inspiration followed by an expiration at functional residual capacity; (2) a “blast” of exhalation; and (3) continued complete exhalation until the end of test [8]. First, the patient should exhale until he or she reaches the functional residual capacity and then be instructed to inhale rapidly and completely. In this phase, the mouthpiece should be placed in the patient’s mouth and indications should be given for the patient to blow as much and as fast as possible and to keep blowing until totally emptying the lungs. Spirometry has been described as a cost-effective, simple, reliable, valid and easy-to-interpret bedside measure [8]. The most used pulmonary function parameter is the forced expiratory volume in the first second (FEV₁), followed by the forced vital capacity (FVC) and the ratio between FEV₁/FVC. Measurements are taken considering patient’s gender, age, height, weight and race and are then compared with predicted values.

Spirometry, namely FEV₁, has been used to assess the effectiveness of respiratory physiotherapy interventions. However, contradictory findings have emerged. Pfleger et al. (1992) found significant improvements in FEV₁ after autogenic drainage and high-pressure PEP-mask (n=14,
Cohen’s d, 0.09 and 0.22) [9]. Jarad, Powell and Smith (2010) reported a statistically significant reduction in FEV1 following hydro-acoustic therapy (n=19, Cohen’s dz=0.12) or flutter (n=19, Cohen’s dz=0.06) [10]. Nevertheless, these changes returned to baseline on the second study day [10].

In two recent reviews where conventional physiotherapy [11] and the active cycle of breathing techniques (ACBT) [12] were compared with other airway clearance techniques, no significant differences were observed between the techniques in terms of pulmonary function measured with spirometry [11]. Nevertheless, when oscillating devices for airway clearance were used, significant results were observed in pulmonary function, the FEV₁ being the primary outcome measure more frequently reported [13].

Findings in the literature about the effectiveness of respiratory physiotherapy interventions in CF remain controversial when FEV₁ is considered as the outcome measure. This is in part due to the fact that accuracy and sensitivity of spirometry depends on many factors that are difficult to control and not related to the intervention itself. Some examples of these factors are the transducer characteristics, presence or absence of an in-line filter, presence or absence of a display, patient’s mood and motivation to cooperate, relationship between the patient and the technician, among others. Therefore, spirometry might be unsuitable or its reliability may be affected in a number of situations, for example if the equipment or settings change, if patients are unwilling or unable to collaborate (e.g. children, people with dementia), or if pain or discomfort is present. Hence, this measure should be routinely used to characterise the pulmonary function of patients with CF, but not to assess the effectiveness of respiratory physiotherapy interventions.

2.1.2. Respiratory sounds

Lung auscultation, performed with conventional stethoscopes, is one of the oldest and most used techniques to diagnose and monitor respiratory diseases [14, 15]. It consists in acquiring acoustic signals from the lung structures during spontaneous or controlled volume or flow breathing, and classifying the respiratory sounds as normal or abnormal (e.g., adventitious respiratory sounds, such as crackles and wheezes) [15]. Auscultation is recognised as an efficient and safe method for the early detection of respiratory diseases as it is non-invasive, practical, low cost and easy to apply in all clinical settings and patients, irrespective of patients’ age and severity of the disease [14-16].

The efficiency of this method depends on the hearing ability of the health professionals [17], their capacity to memorise different sound patterns [18] and on the quality of the acoustic properties of the stethoscope being used [17]. Considering these limitations and subjectivity, reliability studies have been performed. In CF there are no reliability studies using conventional stethoscopes. However, in other respiratory diseases, poor to fair correlations between different raters have been reported, either in taped recorded sounds (kappa=0.26 and coefficient of reliability of less than 60%) [19, 20] and real-time auscultation (–0.02<kappa<0.77) [21]. Using digital stethoscopes, one study conducted in adult patients with CF assessed the inter-rater agreement between real-time manual annotation of respiratory sounds and automatic detection of respiratory sounds through a computerised system [22]. Poor to moderate


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