

TRENT MEDICINES INFORMATION SERVICE

UPDATE ON NEW DEVICES

Flutter[®] device for mucus clearance

Background and Introduction

This newsletter designed to provide information on new medical devices that enter the healthcare market and which may be prescribed. Information on new devices is often hard to get, independent evaluations may be scarce and devices can be expensive. There may also be a patient demand driven by interest groups.

Device name and manufacturer

The 'Flutter' device was first listed in MIMS in July 2012 (distributor by Clement Clarke Ltd), when it was also listed in the Drug Tariff. Other distributors sell this product direct to the public on the internet. Similar devices causing vibration in the airways but not listed in the Drug Tariff are the Acapella[®] and Cornet[®].

What is the Technology

The handheld device consists of a steel ball in a plastic holder that resembles a smokers' pipe. Exhaling into the device causes the steel ball to oscillate and vibrate in the casing. The resulting vibrations that are set up are thought to travel back into the lungs, vibrating the walls of the lungs and encouraging loosening of mucus. This then facilitates clearance of mucus by coughing. It is normally used for 5 to 15 minutes at a time, twice daily. More details can be found on the manufacturers website.¹

What is the device intended to do?

The device is intended for use in medical conditions where there is excessive production of mucus and/or where mucus clearance is reduced, including cystic fibrosis and bronchiectasis.

What is the evidence for effectiveness of the device?

A Cochrane evaluation of clinical studies of oscillating devices in assisting mucus clearance in patients with cystic fibrosis was published in 2009, it included 708 participants in trials.² This did not find a significant difference in effect between oscillating devices and other methods of airway clearance on FEV₁ or other lung function parameters. Where a statistically significant change in secondary outcome variables was found, e.g. on sputum volume or weight, this was small and not wholly in favour of oscillating devices. No data have been published on long term clinical outcomes. A randomised trial of 17 patients with bronchiectasis compared Active Breathing Technique for mucus clearance with the Flutter device for 4 weeks.³ No significant differences between the treatments were identified in lung function, health status measured by questionnaire, sputum weight or breathlessness though 11 of the 17 patients said they preferred the Flutter device.

The British Thoracic Society guidelines for non-Cystic Fibrosis Bronchiectasis⁴ say that oscillation devices such as the flutter should be considered for use with postural drainage and forced expiration when helping patients develop effective mucus clearance techniques.⁴

Any contra-indications?

The distributor lists right-sided heart failure, pneumothorax, TB and haemoptysis as contra-indications to use.

Costs.

Cost per unit: £40.50 (Drug Tariff, June 2013). Cost of purchase by a patient would be higher as it would involve addition of VAT.

It is unclear how long a device lasts and several would probably be needed each year with regular use.

Useful Links

Distributor's website: http://www.clement-clarke.com/products/mucus-clearancespacer/flutter

References

1. Axscan Scandipharm Inc. Fluttter mucus clearance device instructions. <u>http://www.aptalispharma.com/pdf/flutter.pdf</u>, accessed 22/5/13

2. Morrison L, Agnew J. Cochrane Database Syst Rev. 2009 Jan 21;(1):CD006842. doi: 10.1002/14651858.CD006842.pub2 accessed via http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006842.pub2/abstract;jsessionid=B4B7588AFA6A37D0D2A709100F32F5E3.d04t03

3. Thompson C et al. Randomised study of the Flutter device. <u>Thorax.</u> 2002 May;57(5):446-8, accessed via <u>http://thorax.bmj.com/content/57/5/446.long</u>

4. BTS guideline for non-CF bronchiectasis Thorax 2010;65:i1-i58 at http://www.brit-thoracic.org.uk/Portals/0/Guidelines/Bronchiectasis/non-CF-Bronchiectasis-guideline.pdf, (page i30) accessed 22/5/13