

HTA - - Health Technology Assessment Report

The effect of inhaled hypertonic saline on lung structure in children aged 3-6 years with cystic fibrosis (SHIP-CT): a multicentre, randomised, double-blind, controlled trial.

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Author: Tiddens HAWM

List of included studies (2)

Rottier et al (2009); Hubert et al (2009)

Participants

Rottier (n=15); Hubert (n=25)

Outcome measures

Rottier's study evaluated the following parameters: volume median diameter in microns; relative span of the size distribution; delivered dose; total nebulisation time; average output rate. Hubert's study evaluated the following parameters: delivery of a tobramycin (TOBI) solution for inhalation via the eFlow[®] Rapid nebuliser compared to the LC Plus[®],^ç nebuliser.

Main results

Hubert's study's main results were: The mean nebulisation times were significantly shorter for the eFlow[®] Rapid compared to those obtained with the LC Plus[®],^ç on Day 1 and Day 15; Patient compliance was high for both groups using both devices; The maximum TOBI concentration on Days 1 and 15 for the eFlow[®] was 981 $\hat{\pm}$ 1191 and 1575 $\hat{\pm}$ 2182 $\hat{\pm}$ 1/4g/g, respectively, and were 754 $\hat{\pm}$ 927 and 769 $\hat{\pm}$ 823 for the LC Plus for Day 1 and 15, respectively; peak concentrations of TOBI in sputum were achieved in similar times by both devices; 19 and 16 patients reported mild to moderate adverse events associated with the inhalation of TOBI with the eFlow[®] and the LC Plus[®],^ç device, respectively; Adverse events included headache, cough, dyspnoea and abdominal pain, however none were considered serious enough to discontinue treatment. Rottier's study's main results were: the eFlow[®] device delivers an aerosol which contains larger droplets of medication in a narrower size range (less variability) than the LC Plus. The Pari eFlow[®] Rapid costs approximately \$1,740, compared to \$440 for a conventional nebuliser

Authors' conclusions

There was a dearth of comparative evidence describing the use of the eFlow[®] nebuliser device for the treatment of cystic fibrosis patients. Both of the included studies reported shorter nebulisation times in comparison to conventional compressor nebulisers, which should translate into greater patient compliance and therefore improved therapeutic outcomes. However, this conclusion cannot be supported by the evidence included for assessment in this summary. Studies with long-term endpoints are required to confirm this speculation. Consideration should also be given to the large number of other nebulisation devices that are coming onto the market, including the eFlow[®]. In addition, the safety and effectiveness of the device needs to be considered when different pharmaceuticals are used -

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See also

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Keywords

Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy;