

HTA - - Health Technology Assessment Report

Long-term amikacin liposome inhalation suspension in cystic fibrosis patients with chronic *P. aeruginosa* infection.

Code: PM34144923

Year: 2021 Date: 04-Mar-2010

Author: Bilton D

Study design (if review, criteria of inclusion for studies)

All randomized controlled trials including those of parallel and crossover design; systematic reviews and/or meta-analyses. Exclusion Criteria: abstracts were generally excluded because their methods could not be examined; however, abstract data was included in several Cochrane meta-analyses that are presented in this paper; studies of less than seven days duration (including single treatment studies); studies which did not report primary outcomes; studies in which less than 10 patients completed the study.

List of included studies (13)

Tyrrell (1986); Van Asperen (1987); Steen (1991); Mcllwaine (1997); Arens (1994); Bauer (1994); Homnick (1995); Homnick (1998); Gondor (1999); van Winden (1998); Mcllwaine (2001); Newbold (2005); Oermann (2001)

Participants

Tyrrell (1986): n=16; Van Asperen (1987): n=10; Steen (1991): n=24; Mcllwaine (1997): n=36; Arens (1994): n=46; Bauer (1994): n=51+22 X-over; Homnick (1995): n=16; Homnick (1998): n=33; Gondor (1999): n=20; van Winden (1998): n=22; Mcllwaine (2001): n=32; Newbold (2005): n=42; Oermann (2001): n=24

Interventions

Tyrrell (1986): CCPT 1 mo X PEP 1 mo No washout; Van Asperen (1987): CCPT 1 mo X PEP 1 mo No washout; Steen (1991): CCPT 1 mo X PEP 1 mo No washout; Mcllwaine (1997): CCPT 12 mo vs. PEP 12 mo; Arens (1994): CCPT (mean 16.2 d) vs. HFCC (mean 16 d); Bauer (1994): CCPT (mean 12.5 d) vs. MP (mean 11.4 d); Homnick (1995): CCPT 6 mo vs. AOD 6 mo; Homnick (1998): CCPT (mean 8.8 d) vs. AOD (mean 8.9 d); Gondor (1999): CCPT (mean 17.9) vs. AOD (mean 16.6); van Winden (1998): PEP 2 wk X AOD 2 wk 1 wk lead-in/ washout; Mcllwaine (2001): PEP 12 mo vs. AOD 12 mo; Newbold (2005): PEP 13 mo vs. AOD 13 mo; Oermann (2001): HFCC 4 wk X AOD 4 wk 2 wk lead-in/washout

Outcome measures

Primary outcomes under review were forced expiratory volume (FEV-1), forced vital capacity (FVC), and forced expiratory flow between 25%-75% (FEF25-75). These pulmonary function outcomes were consistently evaluated as primary outcomes of interest across the majority of trials under review. Values were obtained as percentage predicted (corrected for age and height) due to the potential for variation among participant age groups (trials were mostly conducted in young, growing children). Secondary Outcomes included number of hospitalizations, adherence, patient preference, quality of life and adverse events. All outcomes were decided a priori. Expecterated secretions such as mucus, sputum, phlegm, dry or wet weight, or volume were not assessed as these outcomes are usually only measured in single treatment studies or trials of short duration (less than one week). Additional literature also fails to prove a strong association between expecterated sputum volume and pulmonary function or clinical status.

Main results

1. Moderate quality evidence suggests that PEP is at least as effective, or more effective, than CCPT according to the primary outcomes of pulmonary function.
2. Moderate quality evidence suggests that there is no significant difference between PEP and handheld AODs according to the primary outcomes of pulmonary function; however, secondary outcomes may favour PEP.
3. Low quality evidence suggests that there is no significant difference between AODs or HFCC/MP and CCPT, according to both primary and secondary outcomes.
4. Very low quality evidence suggests that there is no significant difference between handheld AOD and CCPT according to the primary outcomes of pulmonary function.
5. Adverse events arising from the use of airway clearance devices are mild or negligible, and easily managed by discontinuing device use and treating symptoms.
6. Budget impact projections show that PEP and handheld AODs are highly economically feasible.

Authors' conclusions

There is currently a lack of sufficiently powered, long-term, parallel randomized controlled trials investigating the use of ACDs in comparison to other airway clearance techniques. Unfortunately, it is unlikely that there will be any future trials comparing ACDs to

CCPT seeing as withholding therapy using an ACD may be seen as unethical at present.

<http://dx.doi.org/10.1016/j.jcf.2021.05.013>

See also

J Cyst Fibros. 2021 Nov;20(6):1010-1017. doi: 10.1016/j.jcf.2021.05.013. Epub 2021 Jun 16.

Keywords

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