Bromhexine and topical nasal decongestants for cough and colds in children

Efficacy information- part 2

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Bromhexine

- Mucolytic
  - For conditions with abnormal mucus secretion and impaired mucus transport (breaks up the phlegm)

- Boehringer
  - 28 studies, 1441 exposures
  - Mixed conditions – including asthma, pneumonias
  - Mixed formulations – in 9 studies no longer available
  - Small studies – 25 of the studies had less than 55 participants
Bromhexine

  - 3 to 12 years old
  - 8 days treatment
  - N = 30 (15 in each arm)
  - Acute sinus inflammation (included whooping cough, measles complications etc)
  - All patients received amoxicillin
  - Used 5- Likert scale for nasal secretions, rhinitis score
  - Outcome statistically favored bromhexine – but
    - baseline characteristics did not appear balanced (baseline pain = 2/15 in bromhexine group; 5/15 in placebo)
    - Effect most evident at day 4 to 6 (? Slow onset of
Bromhexine

  - Asthma
  - 3 to 14 year old
  - Two weeks, nebulised
  - NSD compared to saline
- Stewart et al (1985)
  - OME
  - 3 to 8 year olds (n = 95; 190 ears; 380 treatments)
  - Four week courses
  - NSD compared to placebo
- Ambroxol (metabolite)
  - Cystic fibrosis, paediatric, AOM, respiratory distress syndrome
Mucolytic - letostein

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Topical nasal decongestants

- Xylometazoline (Otrivine®)
- Oxymetazoline
- Phenylephrine
- Ipratropium (Atrovent®)
Xylometazoline

- 4 x RCTs
  - 2 positive
    - 10 to 75 years, for allergic rhinitis and included sodium cromoglycate. Fradis et al. (1987)
    - 12 to 75 years for tympanic membrane perforation. Jensen et al. (1990)
  - 2 NSD
    - Both had adjunctive amoxicillin and were for chronic maxillary sinusitis Otten & Grote (1988) (1990)

- 8 studies but no placebos
Xylometazoline

- Michel et al (2005)
  - Rhinosinusitis
  - Mineral salts (n = 66) vs xylometazoline (n = 66)
  - 2 to 6 year olds
  - 14 days treatment
  - NSD (both groups improved by 2 weeks; mineral salts better at 1 week)

  - OME and ventilation tubes
  - N = 80
  - NDS on ventilatory or the protective function of the Eustachian tube)
Phenylephrine

- Turner & Darden (1996)
  - Common cold – measuring middle ear pressure
  - 6 to 18 months old
  - Treatment of nasal obstruction with topical adrenergic decongestants does not improve abnormal middle ear pressures during the common cold
Cochrane reviews
Acute respiratory infections
• Summary of Clinical trials in Children

○ Mucolytics
  • Bromhexine 0
  • Letostein 1
    • Acute febrile bronchitis, N=40. lower cough score in active treatment group cf placebo. (Nespoli et al 1989).

○ Topical nasal decongestants
  • Imidazoline, anticholinergics 0
Bromhexine and topical nasal decongestants

- A paucity of good clinical trials
- A paucity of evidence of efficacy