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*i*CAHE JC Critical Appraisal Summary

Journal Club Details

Journal Club	Royal Hobart Hospital (Cystic Fibrosis)
JC Facilitator	Gaylene Bassett and Nicole Micallef
JC Discipline	Multidisciplinary

Clinical Scenario

How does mannitol compare with hypertonic saline in improving outcomes of patients with cystic fibrosis?

Review Question/PICO/PECO

P Patients with cystic fibrosis

I Mannitol

C Hypertonic saline

O pulmonary function tests, quality of life

Article/Paper

Bilton D, Robinson P, Cooper P, et al (2011) "inhaled dry powder mannitol in cystic fibrosis: an efficacy and safety study" *ERJ express*, doi: 10.1183/09031936.00187510

Please note: due to copyright regulations CAHE is unable to supply a copy of the critically appraised paper/article. If you are an employee of the South Australian government you can obtain a copy of articles from the DOHSA librarian.

Article Methodology:	Randomised Controlled Trial
Journal Club Meeting on:	10 May 2011

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Ques No.	Yes	Can't Tell	No	Comments
1	✓			***Did the study ask a clearly focused question?*** *Population*: Patients with confirmed cystic fibrosis; aged 6 years and above with baseline FEV1 of ≥ 30 and < 90% predicted. Exclusion criteria included failing a mannitol tolerance test (MTT) at screening, concurrent use of hypertonic saline or beta-blockers, pregnancy or breastfeeding, and intolerance of beta-agonists. *Intervention*: Group A—400mg inhaled dry powder mannitol bid; Group B—50mg dose of mannitol (sub-therapeutic dose) *Outcomes:* FEV_1, percentage of responders at 2 weeks, other lung function parameters, pulmonary exacerbations, antibiotic use, quality of life
2	✓			***Was this a randomised controlled trial and was it appropriately so?*** This study was a randomised controlled trial which was an appropriate study design given the objectives of the study. Is it worth continuing: YES
3		✓		***Were participants appropriately allocated to intervention and control groups?*** Whilst this study reported that participants were randomised into intervention and control groups, it did not mention how randomisation was undertaken. The use of unequal randomisation is an important methodological feature of a trial, and therefore a study should give a reason for its use---which was not provided in the current study. A possible reason why this study used unequal randomisation is to increase the amount of information about the 'new' treatment, given that the study is a phase III trial which reports on safety and adverse event data.
4	✓			***Were participants, staff and study personnel 'blind' to participants study group?*** The study was double blinded, which means that neither the participants nor the researchers know who belongs to the control or intervention group.
5		✓		***Were all of the participants who entered the trial accounted for at its conclusion?*** Only 112 (mannitol group) and 86 (control) of the initial 177 (mannitol) and 118 (control) completed the double-blind phase of the study.

6	✓			***Were the participants in all groups followed and data collected in the same way?*** Outcomes were measured and collected in the same way for all participants. All participants were examined at baseline and at 26 weeks.
7	✓			***Did the study have enough participants to minimise the play of chance?*** The study was powered at 80% detect a change in FEV1 from baseline at week 26 of 70 mL in the total intention to treat (ITT) cohort and 85 mL in the subgroup of subjects taking concomitant rhDNase.
8				***How are the results presented and what is the main result?*** Results were presented using p-values and confidence intervals. *Bottom line result* • Airway function in patients with cystic fibrosis can be successfully improved with mannitol. • Mannitol has an acceptable safety profile for patients with cystic fibrosis.
9				***How precise are these results?*** Differences between groups were determined based on p-value computations. Confidence intervals were likewise calculated to determine precision of results.
10				***Were all important outcomes considered so the results can be applied?*** Journal club to provide answers

Summary of search strategy

Key words
Concept 1: 'cystic fibrosis' OR 'cystic disease pancreas' OR mucoviscidosis OR CF
Concept 2: mannitol

Databases
Medline, EMBASE, CINAHL, Academic Search Premiere, PubMed, Health Source, BioMed Central Gateway, ProQuest family health, Science Citation Index Expanded, Health and Medical Complete, TRIP and Google.

Limiters
English articles only, published in the past 10 years

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