A Randomized Controlled Trial of Budesonide versus Acetazolamide on Rapid Ascent: Altitude Sickness Prevention and Efficacy of Comparative Treatments (ASPECT)

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Abstract

Background: Inhaled budesonide has been suggested as novel preventive medication for acute mountain sickness (AMS). However, efficacy has not been validated nor compared to the standard AMS prevention medication acetazolamide.

Methods: This double-blind, randomized, placebo-controlled trial compared inhaled budesonide to oral acetazolamide to placebo, starting the morning of ascent from 1,240 m (4,100 ft) to 3,810 m (12,570 ft) over 4 hours.

Results: 103 participants were enrolled and completed the study; 33 (32%) received budesonide, 35 (34%) acetazolamide, and 35 (34%) placebo. Demographics were not different between the groups (p > 0.09). Total AMS incidence was 73%, with severe AMS 47%. Fewer participants in the acetazolamide group (n=15, 43%) developed AMS compared to both budesonide (n=24, 73%) (OR = 3.5, 95% CI 1.5 – 10.1) and placebo (n=22, 63%) (OR = 0.5, 95% CI 0.2 – 1.2). Severe AMS was reduced with acetazolamide (n=11, 31%) compared with both budesonide (n=18, 55%) (OR = 2.6, 95% CI 1 – 7.2), and placebo (n=19, 54%) (OR = 0.4, 95% CI 0.1 – 1), with a number needed to treat of 4.

Conclusion: Budesonide was ineffective for the prevention of AMS, and acetazolamide was preventive of severe AMS taken just prior to rapid ascent.
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Introduction:
Initial studies suggest inhaled budesonide may be a novel preventative agent for acute mountain sickness (AMS).
- Compare efficacy to standard prophylactic acetazolamide
- Drug efficacy in rapid ascent

Methods:
Double blind, RCT comparing
Inhaled budesonide 180mcg BID
Acetazolamide 125mg PO BID
Control and inhaled placebo

Results:
- N = 103 participants
- 33 (32%) budesonide
- 33 (32%) acetazolamide
- 33 (32%) placebo

Total AMS (HAA=1.5CLo=3): 7%
- Acetazolamide: 15 (45%)
- Budesonide: 24 (73%)
- Placebo: 22 (63%)

Severe AMS (HAA=3.5): 1%
- Acetazolamide: 11 (31%)
- Budesonide: 18 (55%)
- Placebo: 19 (54%)

NNT = 4

Conclusion:
Budesonide was found to be ineffective for the prevention of AMS compared to both placebo and acetazolamide.
Acetazolamide decreased the incidence of AMS when taken just prior to rapid ascent to high altitude, NNT = 4
Smaller increases in ventilation were associated with greater symptoms of AMS. 
BcCO2 is a better AMS predictor than SpO2

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Table 1

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<tr>
<th>Treatment</th>
<th>Mean (SD)</th>
<th>Median (IQR)</th>
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Table 2

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AMS Severity Score:
- Acetazolamide: 3.4
- Budesonide: 4.5
- Placebo: 4.8

AMS Symptom Score (0.52)

dBCO2 had a greater correlation with lower AMS than dSpO2:
r = -0.28, p<0.01
r = -0.19, p<0.05