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## Electronic Letters to:

Original articles: M Bradshaw and A Sen Use of a prophylactic antiemetic with morphine in acute pain: randomised controlled trial Emerg Med J 2006; 23: 210-213 [Abstract] [Full text] [PDF]

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## Electronic letters published:

Is a two fold reduction of vomitting not significant? Franz Piribauer (4 October 2006)

## Is a two fold reduction of vomitting not significant? 4 October 2006

Franz Piribauer, Public Health Consultant Center of applied Epidemiology Vienna Send letter to journal: Re: Is a two fold reduction of vomitting not significant. significant? Email Franz Piribauer

Dear Editor

Sir, the fine clinical study of Bradshaw and Sen on the usefulness of antiemetics when administering morphine in emergency situations provides interesting data. In my view their data do not support the conclusions of the authors completely.

They reported a more than twofold increase of side effects (nausea/vomiting) in patients without antiemetic prophylaxis as non-

The study is too small to rule out that the observed relative risk increase from 1,6% to 3,7% is due to chance or not. Calculating the 95% confidence interval from their data, the real rate for the antiemetic-free group could have been somewhere between 1,2% - 8,3%.

Of course if we accept a cumulative incidence of up to 8% side effects in acute pain patients, and we do not want to bring it down, then the study gives a satisfying answer. If we want to prove statistically that the observed effect of a reduction from around 4% to 2% is really due to chance, then a study size of around 2500 is necessary (usual assumptions: 95% confidence level, 80% power, 1:1 balance of unexposed: exposed). Smaller sample sizes will always produce non-significant results when rates are so small. Alas, for clinical practice, even if a larger study proves the reduction to be robust, the number needed to treat would be quite large as rates and their differences are small.

For calculating the confidence intervalls I used STATA 9.0, (cii command, assumption of binomial distribution) and for the sample size estimate the STATCALC program of EPI Info Version 6, CDC, Atlanta.

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