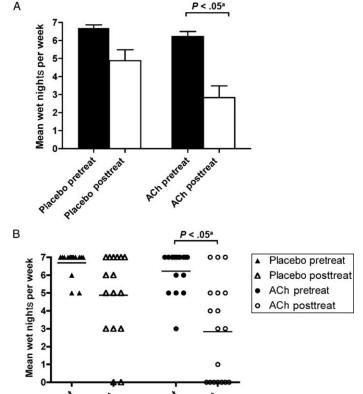
Enuresis (bedwetting) is a common problem in children. One (not very effective) treatment for enuresis is desmopressin (antidiuretic hormone), which helps reduce urine production by making the urine more concentrated. Austin et al [1] studied the effect of adding treatment with tolteridine, a long-acting an anticholinergic (ACh) medication, to desmopressin among children with enuresis not responding to desmopressin.

a.) The results section of the paper includes the following sentence:

"After 1 month of therapy, we found a significant reduction in the mean number of wet nights in the combination therapy group receiving long-acting tolterodine, compared with placebo (Fig 2)."

Figure 2 from that paper is reprinted below. Using just that figure, do you agree with how that



sentence summarizes the results? If not, how would you correct it? [3]

Since we don't give you the correct P-value, which would compare the change between the groups, rather than just within groups the best we can say is that there was a statistically significant (P<0.05) decline in the number of wet nights per week in the ACh group (by about 3), but not in the placebo group (about 1.5).

b.) Would you classify this outcome variable (mean wet nights per week) as a surrogate outcome? Explain. [2]

No, this is a relevant outcome that patients can notice and measure themselves, so I would not classify it as a surrogate outcome. (An example of a surrogate outcome would be the specific gravity of the urine.)

c.) Do you agree with the following statement? Explain your answer.

"The difference between groups was statistically significant but not clinically significant." [2] I disagree because they have not shown a statistically significant difference.

Permission to reprint figure pending.

REFERENCES

1. Austin PF, Ferguson G, Yan Y, Campigotto MJ, Royer ME, Coplen DE. Combination therapy with desmopressin and an anticholinergic medication for nonresponders to desmopressin for monosymptomatic nocturnal enuresis: a randomized, double-blind, placebo-controlled trial. Pediatrics. 2008;122(5):1027-32.