Pain, 33 (1988) 133
Elsevier

PAI 01204

Ann Arbor, MI, 2 December 1987

re, Trazodone in dysaesthesia — a reply

Dear Editor,

This is in response to the comments made by Dr. Tyrer and Mr. Matthews regarding the above manuscript. First, sample size calculations were based on a percent reduction in the pain measures generated from the McGill Pain Questionnaire which was administered serially during the course of the study.

(1) These calculations were performed using STPLAN, a program developed at the University of Texas Medical Center/M.D. Anderson Hospital for calculation of sample size in clinical trials.

(2) Assuming an α of 0.05 and a power of 80%, using a one-sided Student's t test, the following chart was generated:

% Reduction in pain measure(s)		Sample size in each group
Placebo	Trazodone	
20	50	8/group
30	60	9/group
30	70	6/group

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We assumed that patients that were randomized to placebo would experience a temporary reduction in quantitative and/or qualitative pain measures. We also assumed a very large reduction in pain complaints would be achieved for those patients randomized to active drug.

Regarding the analysis of compliance and side-effects between groups, we agree that a Fisher's Exact Test would have been the more appropriate test to use. There was no significant difference between patient groups regarding side-effects. However, the trend for increased side-effects in the active drug group cannot be ignored, particularly in a patient sample with a precariously balanced neurogenic bladder and other neurophysiologic sequelae from a spinal cord injury. Perhaps in a neurologically intact cohort this would present far less a problem.

Thank you for the opportunity to respond to the above-mentioned letter.

Gary Davidoff