A RANDOMIZED TRIAL OF VARENICLINE (CHANTIX) FOR THE TREATMENT OF SPINOCEREBELLAR ATAXIA TYPE 3

Alessandro Filla, Francesco Sacca, Giuseppe De Michele, Napoli, Italy: Zesiewicz et al.1 reported that varenicline improved ataxia in patients with spinocerebellar ataxia type 3 (SCA3), yet the following issues should be considered.

1. Why did the authors use the Fisher test for comparison of baseline characteristics (table 1)? Patients in the placebo group appeared to be older and more severely compromised. For this reason, wouldn’t the subjects respond less to treatment? Blocked randomization may have prevented unequal distribution between groups.

2. The number of patients was small. Furthermore, due to the large number of dropouts in the placebo group, the authors could not complete the originally planned crossover study. This weakens the study and its results. Power calculation, which also accounts for patient dropout, was not performed.

3. Primary efficacy measures included all the SARA subscores and there were no corrections made for multiple comparisons. The SARA subscore for gait improved more in the varenicline group (table 2'), but stance improved more in the placebo. Can the authors explain this discrepancy? In controlled trials, it is preferable to choose a priori a single, major study endpoint.

4. Beck Anxiety Inventory score improved in the varenicline group. Could mood improvement contribute to better performance for SARA?

This article contributes to the study of degenerative ataxias where effective treatments are lacking and new strategies are needed. However, the results of the study should be taken cautiously. This trial might be considered more a safety trial than a study on efficacy. Results of drug efficacy should be obtained in a larger study that complies with the guidelines of a well-designed, controlled, randomized trial.

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nosis in challenging patients. Studies show that DaTSCAN improves confidence in diagnosis and management in clinically uncertain parkinsonian syndromes. Cancer risk from any scan cannot be ignored. The 1 in 7,500 possible cancer risk has to be compared to the greater chance of psychological trauma of a false-positive PD diagnosis or the functional disability that may result from a missed PD diagnosis.

Author Response: Raul de la Fuente-Fernandez, Ferrol, Spain: Dr. Bajaj states that I painted “a rosy picture” of clinical diagnostic accuracy in PD. This may be. I am color blind. To put the problem into perspective, let me quote Spinoza: “He who would distinguish the true from the false must have an adequate idea of what is true and false.”

Unfortunately, there is no current evidence regarding the clinical utility of DaTSCAN in PD. Considering the study by Bajaj et al., I wonder who was right: Reviewer 1? Reviewer 2? DaTSCAN image readers? Assuming that DaTSCAN imaging represented the truth, the whole truth, and nothing but the truth, the overall accuracy of the clinical diagnosis was still rather high (approximately 80%), even in that set of difficult tremor cases.

I agree that DaTSCAN may improve doctors’ confidence in diagnosis and management. However, patients do not seem to feel any difference. If this is confirmed, the consent form should perhaps read: “This test involves some radiation-related risks and you will not obtain any benefit. But your doctor will feel much better.”