



ASSESSING PATIENTS' ACCESS TO TETRABENAZINE (XENAZINE) AFTER FDA APPROVAL

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OBJECTIVES

To assess patient satisfaction with regard to current accessibility of the drug as compared to prior utilization through Investigational Exemption for a New Drug, granted to Dr. Jankovic in 1979.

BACKGROUND

In 2008, the monoamine depleting drug tetrabenazine (Xenazine) was approved by the FDA for the treatment of the chorea associated with Huntington disease (HD). The drug is now available as an orphan therapy through specialty pharmacies.

METHODS

A self-administered questionnaire was constructed to assess patients' experiences, costs, and attitudes related to perceived efficacy and tolerability of tetrabenazine prescribed for the treatment of a variety of hyperkinetic movement disorders. A mail survey was then conducted using as study population all the patients currently enrolled in the tetrabenazine treatment program at the Baylor College of Medicine Parkinson's Disease Center and Movement Disorders Clinic (PDCMDC).

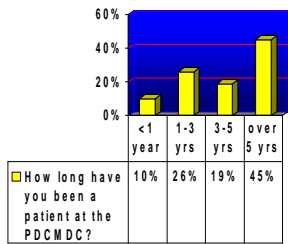
RESULTS

The questionnaire was mailed to 263 patients; 117 (44.5%) patients returned the questionnaires and were included in the analysis. The respondents included 39 (33.3%) patients with Tourette syndrome, 34 (29.1%) patients with tardive dyskinesia, and 23 (19.7%) patients with HD. Tetrabenazine use for more than 5 years was reported by 37 (31.6%) respondents. Prior to taking tetrabenazine, 106 (90.6%) patients indicated their symptoms made them moderately to severely ill and symptoms were reported improved in 108 (92.3%) patients with tetrabenazine. 113 (96.6%) patients were currently taking tetrabenazine, with a mean daily dosage of 61.1 ± 26.9 mg. Some side effects from tetrabenazine treatment were reported by 82 (70.1%) patients and included drowsiness (54.9%), slowness of movement (31.7%), restlessness (14.6%) and depression or mood change (12.2%). Before FDA approval, 97 (82.9%) patients purchased the drug from the PDCMDC. With the current Specialty Pharmacy Program, 82 (70%) patients were initially approved for coverage of tetrabenazine by their insurance carrier; most of the other claims were successfully appealed. Before FDA approval 57 (48.7%) of patients were paying \$200-\$300 per bottle, but since the FDA approval 89 (76.1%) have less than \$100 out-of-pocket cost. Of the responders, 100 (85.5%) patients stated that they were satisfied or very satisfied with their response to tetrabenazine and 91 (77.8%) with the Specialty Pharmacy Program.

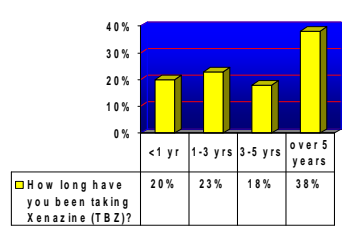
CONCLUSIONS

Our survey indicates a high level of satisfaction among patients prescribed tetrabenazine for their hyperkinetic movement disorder with cost-effective access to the drug via a specialty pharmacy system.

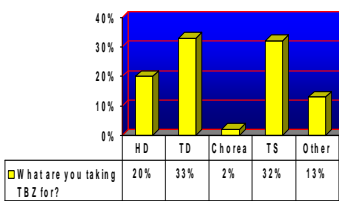
How long have you been a patient at the PDCMDC?



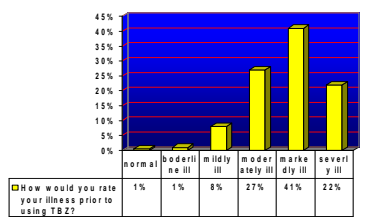
How long have you been taking tetrabenazine (Xenazine)?



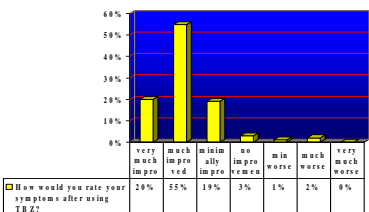
What are you taking tetrabenazine (Xenazine) for?



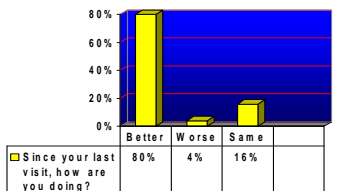
How would you rate your overall illness PRIOR using tetrabenazine (Xenazine)?



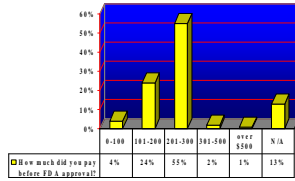
How would you rate your symptoms AFTER using tetrabenazine (Xenazine)?



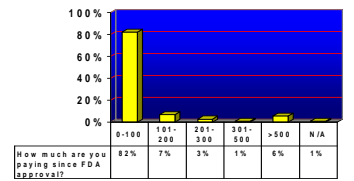
Since your first visit to the clinic, would you say that you are feeling better, worse or about the same at this time?



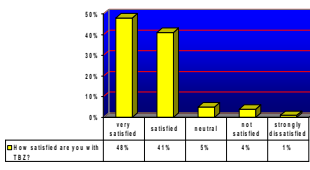
About how much did you pay per bottle of tetrabenazine (Xenazine) BEFORE it was FDA approved?



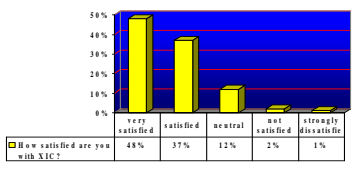
How much is your current out-of-pocket expense for tetrabenazine (Xenazine) NOW that it has been FDA approved and is available through the current program?



How would you rate your overall satisfaction with tetrabenazine (Xenazine)?



How would you rate your overall satisfaction with Xenazine Information Center?



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