Microscopic Hematuria in Patients on Tecfidera®

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OBJECTIVE

To assess the prevalence of microscopic hematuria occurring in patients taking Tecfidera®.

BACKGROUND

Tecfidera® (dimethyl fumarate) was FDA approved for use in persons with MS in March of 2013. While proteinuria was identified in 29 (8%) of patients on Tecfidera® at the dose of 240 mg twice daily in the pivotal clinical trials[1], hematuria was not identified as an adverse event. During routine surveillance of urinalysis for patients on Tecfidera® the incidental observation of microscopic hematuria was made.

METHODS

A baseline urinalysis was obtained prior to starting Tecfidera® and repeat urinalyses were obtained every 3 to 6 months while patients remained on Tecfidera®. For purposes of this analysis, only patients with a known normal baseline urinalysis were included (n = 76). Additionally, patients included had no known history of renal dysfunction, hematuria or coagulopathy.

REFERENCES

Biogen Idec's TECFIDERA® (Dimethyl Fumarate) Approved in US as a First-Line Oral Treatment for Multiple Sclerosis. Biogen Idec Press Release. Mar 27, 2013

Lexicomp Online, Lab and Formulary Manual, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2015; November 7, 2016.

RESULTS

Microscopic hematuria was defined as the finding of 12 or more RBCs/uL on urinalysis[2]. Following initiation of Tecfidera® 23 patients were found to exhibit microscopic hematuria on at least one occasion. In 16 patients, an identifiable cause of microscopic hematuria was found, including urinary tract infection, menstruation and other genitourinary causes. However, 7 patients (9%) exhibited microscopic hematuria on at least one or more occasion that could not be attributed to another cause. Patients with recurring, unexplained microscopic hematuria were referred to nephrology for evaluation and no underlying renal pathologies were identified.

Demographics

Age	44.86 (mean) 26-55 (range)
Gender	Female = 6 Male = 1
EDSS	1.57 (mean) 1-2.5 (range
MS disease duration in years	15.9 (mean) 3-30 (range)
Total length of time on Tecfidera® in years	3 (mean) 2.2-3.7 (range)
Length of time on Tecfidera® when first occurrence of hematuria	10.8 months (mean) 9-16 months (range)

Urinalysis Results

Patient	RBCs/uL
1	19-67
2	13
3	20-21
4	15-77
5	12-20
6	20
7	15-17

CONCLUSION

This small, uncontrolled, observational study suggests a possible causal association between Tecfidera® and the development of microscopic hematuria.