

Lysteda Has QOL Benefits in Menorrhagia

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FROM THE ANNUAL MEETING OF
THE AMERICAN SOCIETY FOR
REPRODUCTIVE MEDICINE

DENVER – A novel oral formulation of tranexamic acid provided immediate and enduring improvement in two quality of life measures among women with menorrhagia in a large open-label study.

The improved quality of life benefits

were noted during the first menstrual cycle after initiating treatment.

Also, the benefits were maintained throughout the 15-cycle study, Dr. Ken Muse reported at the meeting.

Tranexamic acid is a lysine analogue that acts as a competitive plasmin inhibitor and an antifibrinolytic agent. The oral formulation was approved by the Food and Drug Administration late last year for the treatment of cyclic heavy

menstrual bleeding and is marketed under the trade name Lysteda.

It's a valuable alternative to surgical or hormonal treatments for this disorder, which affects up to 22 million Americans, said Dr. Muse of the University of Kentucky, Lexington.

Oral tranexamic acid won marketing approval on the strength of studies showing it reduced menstrual flow by nearly 40%.

The quality of life study was conducted because what drives many women to consult a physician regarding menorrhagia is the disorder's negative impact on their daily activities.

The study involved 723 women who took oral tranexamic acid at 1.3 g three times per day for a maximum of 5 days per menstrual cycle, starting with the onset of heavy menstrual bleeding.

General quality of life was assessed using the 36-Item Short Form Health Survey. The Aberdeen Menorrhagia Clinical Outcome Questionnaire (AMCOQ) was used as a disease-specific measure of the impact of treatment.

Significant improvements were noted in six of eight SF-36 categories and domains at cycle 15 compared with baseline.

The greatest improvements were in vitality, with a 13.5% gain, and social functioning, with an 8.3% gain.

Patients also showed significant long-term improvements in bodily pain, mental health, role-physical, and role-emotional items. Only physical functioning and general health weren't significantly different at cycle 15 compared with baseline.

Women on oral tranexamic acid had a mean 5.4% long-term improvement in the mental health component of the SF-36, and a less robust but nonetheless significant 1.7% gain in the physical functioning component, according to Dr. Muse.

Oral tranexamic acid was well tolerated. Adverse events deemed by investigators to be probably or definitely treatment related occurred in 7.3% of subjects; these were mild to moderate in nature and most often consisted of headache, menstrual discomfort, or back pain. There were few gastrointestinal side effects, and no thrombotic or thromboembolic events.

Scores on the AMCOQ indicated patients had a consistent improvement in daily activities that are affected by cyclic heavy menstrual bleeding. ■

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VITALS

Major Finding: Six of eight SF-36 categories and domains improved significantly at cycle 15 compared with baseline. Scores on the AMCOQ indicated patients experienced a consistent improvement in daily activities that are impacted by cyclic heavy menstrual bleeding.

Data Source: An open-label study of quality of life in 723 women who took oral tranexamic acid at 1.3 g three times per day for a maximum of 5 days per menstrual cycle, starting with the onset of heavy menstrual bleeding.

Disclosures: The study was funded by Xanodyne Pharmaceuticals and Ferring Pharmaceuticals, which acquired global marketing rights to Lysteda last May. Dr. Muse disclosed that he has received research grants and served as an adviser to Xanodyne.

*See MOC section on SDEF website for details

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