Efficacy of tranexamic acid in the treatment of idiopathic and non-functional heavy menstrual bleeding: a systematic review

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CRD summary
The review concluded that tranexamic acid was a safe and effective therapy for the treatment of idiopathic and non-functional heavy menstrual bleeding and could potentially improve quality of life. The review had some methodological issues and the quality of the evidence base was variable; hence, the reliability and generalisability of the authors’ conclusions is uncertain.

Authors' objectives
To determine the efficacy of tranexamic acid in the treatment of idiopathic and non-functional heavy menstrual bleeding.

Searching
EMBASE and PubMed were searched to February 2011 for articles published in English. Search terms were reported.

Study selection
Studies of tranexamic acid versus placebo, no treatment or any other medical therapy for the treatment of heavy uterine bleeding in non-pregnant women of reproductive age were eligible for inclusion. Heavy menstrual bleeding could be measured objectively or subjectively. Women could have uterine fibroids, dysfunctional uterine bleeding or menorrhagia secondary to an intrauterine device. Studies in women with gynaecological malignancies or post-menopausal bleeding were excluded. The primary outcome was objective reduction in idiopathic and non-functional menstrual bleeding. The secondary outcome was patient quality of life.

The included studies considered tranexamic acid in women with idiopathic menorrhagia, intrauterine device induced menorrhagia, dysfunctional uterine bleeding, uterine fibroids and unspecified menorrhagia. Treatment doses and durations varied across the studies. Comparators varied across the studies and included placebo, mefenamic acid and ethamsylate. The studies were published between 1970 and 2010.

It appeared that both authors were involved in study selection.

Assessment of study quality
Two reviewers independently assessed study validity using the US Preventive Service Task Force grading system.

Data extraction
Data were extracted on reduction in menstrual bleeding, quality of life and adverse events.

The authors did not state how many reviewers extracted data.

Methods of synthesis
A narrative synthesis was presented by outcome and cause of heavy menstrual bleeding.

Results of the review
Ten studies were included in the review (1,465 women, range from 16 to 849): seven RCTs and three observational studies. Four of the RCTs were deemed good quality, two were fair and one was poor. The observational studies were fair to poor quality.

Four studies in women with idiopathic menorrhagia showed that treatment with tranexamic acid was associated with a 33% to 54% reduction in menstrual blood loss compared with baseline. Two studies in women with intrauterine device induced menorrhagia found that treatment with tranexamic acid had mixed results that ranged from an 11.5% increase in bleeding to a 24% decrease. Two studies in women with dysfunctional uterine bleeding showed that treatment with...
Tranexamic acid was associated with a 34% to 60% decrease in menstrual blood loss. Studies in other patient groups reported a reduction in blood loss from baseline ranging from 9% (uterine fibroids) to 95% (menorrhagia; subjective outcome). Tranexamic acid was associated with a 46% to 83% improvement in quality of life outcomes.

No thromboembolic events were reported in any study. Reported adverse events were generally mild to moderate and mostly gastrointestinal.

**Authors’ conclusions**
Tranexamic acid was a safe and effective treatment for the treatment of idiopathic and non-functional heavy menstrual bleeding and could potentially improve quality of life.

**CRD commentary**
Inclusion criteria for the review were clearly defined. A limited search of two relevant databases was undertaken, which may mean that some relevant studies were overlooked. There was potential for language bias, as only articles in English were included. Publication bias was not assessed and could not be ruled out. Attempts were made to reduce error and bias during quality assessment and study selection; it was unclear whether the same methods were used for data extraction.

The quality of the evidence base was variable and there were differences across the studies in terms of patient type and treatment. Most of the studies had small sample sizes (fewer than 100 participants). A narrative synthesis was appropriate, but there was a lack of clarity in the synthesis that made it difficult to interpret the results meaningfully.

The authors’ conclusions reflect the evidence base but the review had some methodological issues and the quality of the evidence base was variable; hence, the reliability and generalisability of the authors’ conclusions is uncertain.

**Implications of the review for practice and research**
**Practice:** The authors stated that it was premature to support use of tranexamic acid in women with heavy bleeding associated with uterine fibroids. The effects in leiomyoma were inconclusive and should be viewed with caution.

**Research:** The authors stated that further research into the effects of tranexamic acid in women with symptomatic fibroids was needed. The impact of fibroid type, size and location needed exploration. Meta-analysis of individual patient data may be useful.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.