**AUB KQ1 Evidence Table (Reference ID #935)**

| **Study Description** | **Intervention(s)/ Comparator(s)** | **Patient Population** | **Baseline Measure(s)** | **Outcome Measure(s)** | **Overall Quality**  **Risk of Bias** |
| --- | --- | --- | --- | --- | --- |
| **Author:**  Preston et al., 1995  **Country:**  United Kingdom  **Enrollment** **period:**  NR  **Intervention** **setting:**  Hospitals and clinics  **Funding:**  Pharmacia  **Author industry relationship disclosures:**  NR  **Study Design:**  RCT, double blind, placebo controlled  **Blinding:**  Patients, clinicians | **Intervention:**  Tranexamic acid  1 gm, 4 times a day on days 1 to 4 and placebo on days 19 to 26  **Comparator:**  Placebo on days 1 to 4 and norethisterone  5 mg twice per day on days 19 to 26  Cycle 1: Placebo  Cycle 2: Placebo  Cycle 3: Treatment  Cycle 4: Treatment  **Groups:**  **G1:** Tranexamic acid  **G2:** Norethisterone  **Followup:**  4 months | **Inclusion criteria:**   * Aged 18 or older * Cycle length 28 ± 7 days * No hormone therapy within previous 3 months * Not taking medication which might affect MBL * No contraindication to either drug * Normal renal function (serum creatinine <125 µmol/l) * Normal pelvic examination * Negative cervical cytology * Menorrhagia (average MBL over 2 cycles >80 ml per cycle)   Regular cycle  **Exclusion criteria:**  See inclusion criteria  **N at enrollment:**  **G1:** 25  **G2:** 21  **N at followup:**  **G1:** 25  **G2:** 21  **Age, mean years ± SD:**  **G1:** 40.6 ± 4.7  **G2:** 39.3 ± 7.1  **BMI:**  NR  **Weight, mean kg ± SD:**  **G1:** 71.2 ± 14.9  **G2:** 63.5 ± 9.2  **G1** **vs. G2:** p<0.048  **Parity, n (%):**  0:  **G1:** 1 (4)  **G2:** 1 (5)  1:  **G1:** 2 (8)  **G2:** 3 (14)  2:  **G1:** 13 (52)  **G2:** 10 (48)  3:  **G1:** 9 (36)  **G2:** 6 (29)  4:  **G1:** 0  **G2:** 1 (5)  **Race/ethnicity:**  NR | **Bleeding:**  MBL measured using the alkaline hematin method at cycles 1 and 2 combined,a mean ml ± SD:  **G1:** 175 ± 84  **G2:** 173 ± 85  Hemoglobin,b mean g/dl ± SD:  **G1:** 12.3 ± 1.2  **G2:** 12.0 ± 1.4  Serum ferritin,b mean μg/l ± SD:  **G1:** 11.2 ± 11.4  **G2:** 8.9 ± 7.2  Transferrin,b mean g/dl ± SD:  **G1:** 3.68 ± 0.42  **G2:** 3.64 ± 0.56 | **Bleeding:**  MBL measured using the alkaline hematin method at cycles 3 and 4 combined,c mean ml ± SD:  **G1:** 97 ± 89  **G2:** 208 ± 135  **G1 vs. BL:** p<0.0001  **G2 vs. BL:** p=0.26  **G1 vs.** **G2:** p<0.0001  MBL estimated reduction from baseline, ml (95% CI):  **G1:** 79 (62, 108)  **G2:** -34 (-64, 2)  **G1 vs.** **G2:** 113 (71, 155)  MBL % change from baseline, mean (range):  **G1:** -45 (-93, 23)  **G2:** 20 (-62, 114)  MBL < 80 ml per cycle, n:  **G1:** 14/25  **G2:** 2/21  Hemoglobin, mean g/dl ± SD:  **G1:** 12.9 ± 0.9  **G2:** 12.6 ± 1.6  Serum ferritin, mean μg/l ± SD:  **G1:** 11.5 ± 6.0  **G2:** 10.3 ± 6.8  Transferrin, mean g/dl ± SD:  **G1:** 3.34 ± 0.34  **G2:** 4.74 ± 0.53  **Quality of life:**  General health, n (%):  Better:  **G1:** 12 (50)  **G2:** 6 (30)  Same/worse:  **G1:** 12 (50)  **G2:** 14 (70)  Amount of flooding and leakage, n (%):  Better:  **G1:** 20 (83)  **G2:** 9 (45)  Same/worse:  **G1:** 4 (17)  **G2:** 11 (55)  **G1 vs. G2:** p=0.008  Limitation of social activities, n (%):  Better:  **G1:** 16 (67)  **G2:** 9 (45)  Same/worse:  **G1:** 8 (33)  **G2:** 11 (55)  **Pain:**  Abdominal pain, n (%):  Better:  **G1:** 9 (38)  **G2:** 4 (20)  Same/worse:  **G1:** 15 (62)  **G2:** 16 (80)  **Sexual function, n (%):**  Better:  **G1:** 11 (46)  **G2:** 3 (15)  Same/worse:  **G1:** 13 (54)  **G2:** 17 (85)  **G1 vs. G2:** p=0.029  **Patient satisfaction:**  Assessment of blood loss during treatment compared to placebo cycle, n (%):  Better:  **G1:** NR  **G2:** NR  Same/worse:  **G1:** NR  **G2:** NR  **G1 vs. G2:** p=0.002d  **Fertility:**  NR  **Time to conception:**  NR  **Additional interventions:**  NR  **Adverse events:**  Dysmenorrhea, %:  **G1:** 80  **G2:** 85  Headache, %:  **G1:** 32  **G2:** 48  Gastrointestinal symptoms including diarrhea, nausea, vomiting, and dyspepsia, %:  **G1:** 12  **G2:** 33  Weight gain, n:  **G1:** 2  **G2:** 0 | **Overall quality:**  Fair  **Risk of bias:**  Randomization:  Low  Allocation concealment:  Low  Selective reporting:  Unclear  Blinding patients/personnel:  Low  Blinding outcome assessment:  Low  Incomplete outcome reporting:  High  Other:  Low |

**Table Notes:** a Data also given for cycles 1 and 2 separately; b Laboratory values are from the pre-placebo phase; c Data also given for cycles 3 and 4 separately; d Patients treated with tranexamic acid were significantly better than those treated with norethisterone.