**AUB KQ1 Evidence Table (Reference ID #1304, #1255)**

| **Study Description** | **Intervention(s)/ Comparator(s)** | **Patient Population** | **Baseline Measure(s)** | **Outcome Measure(s)** | **Overall Quality**  **Risk of Bias** |
| --- | --- | --- | --- | --- | --- |
| **Author:**  Fraser et al., 1981  Fraser et al., 1984a  **Country:**  Australia  **Enrollment** **period:**  NR  **Intervention** **setting:**  NR  **Funding:**  Park-Davis and Co  Australian National Health and Medical Research council  **Author industry relationship disclosures:**  NR  **Study Design:**  RCT (crossover)  **Blinding:**  Patients, clinicians | **Intervention:**  Mefenamic acid  500mg, 3 times/day, onset to end of menses for 2 cycles followed by placebo for 2 cycles  **Comparator:**  Placebo for two cycles followed by mefenamic acid for 2 cycles  **Groups:**  **G1:** Mefenamic acid first then placebo  **G2:** Placebo first then mefenamic acid  **Ga:** Mefenamic acid  **Gb:** Placebo  **Followup:**  4 cycles | **Inclusion criteria:**  Menorrhagia  **Exclusion criteria:**  See inclusion criteria  **N at enrollmenta:**  **G1+G2:** 85  **N at followup:**  **G1:** 38  **G2:** 31  **Age years, mean ± SD:**  **G1+G2**: 33 ± 6.9  **BMI:**  NR  **Parity:**  NR  **Race/ethnicity:**  NR | **Bleeding:**  Menorrhagia duration, mean years ± SD:  **G1+G2:** 11.2 ± 9.4  Dysmenorrhea duration, mean years ± SD:  **G1+G2:** 11.6 ± 8.5  Bleeding days per cycle, mean ± SD:  **G1+G2:** 3.3 ± 1.8  Pain, days per cycle, mean ± SD:  **G1:** 3.1 ± 1.9  **G2:** 3.1 ± 1.7 | **Bleeding:**  MBL measured by alkaline hematin method, mean ml (SE):  All patients (n=69):  **Ga:** 48.1 (4.4)  **Gb:** 66.9 (4.7)  **Ga vs. Gb:** p<0.001  True menorrhagia (n=30):  **Ga:** 77.2 (8.7)  **Gb:** 110 (5.9)  **Ga vs. Gb:** p<0.001  MBL <80 ml (n=39):  **Ga:** 36.9 (3.4)  **Gb:** 45.8 (2.6)  **Ga vs. Gb:** p<0.025  MBL <35 ml (n=14):  **Ga:** 31.6 (7.9)  **Gb:** 24.7 (1.4)  **Ga vs. Gb:** p=NS  MBL measured by alkaline hematin method, mean ml (SE):  **G1a:** 55.2 (4.9)  **G1b:** 69.4 (5.5)  **G2a:** 63.7 (4.7)  **G2b:** 39.8 (4.2)  **G1a vs. G1b:** p<0.05  **G2a vs. G2b:** p<0.001  **G1a vs. G2a:** p<0.02  **G1b vs. G2b:** p<0.4  Bleeding days per cycle, mean (SE):  **Ga:** 4.9 (0.14)  **Gb:** 5.3 (0.14)  **Ga vs. Gb:** p<0.003  **Pain:**  Abdominal pain, days per cycle, mean (SE):  **Ga:** 1.5 (0.13)  **Gb:** 2.1 (0.15)  **Ga vs. Gb:** p<0.001  Headache, days per cycle, mean (SE):  **Ga:** 0.8 (0.14)  **Gb:** 1.6 (0.16)  **Ga vs. Gb:** p<0.001  Nausea, days per cycle, mean (SE):  **Ga:** 0.6 (0.09)  **Gb:** 0.7 (0.10)  **Ga vs. Gb:** p=NS  Diarrhea, days per cycle, mean (SE):  **Ga:** 0.22 (0.06)  **Gb:** 0.45 (0.09)  **Ga vs. Gb:** p<0.008  Depression, days per cycle, mean ± SD:  **Ga:** 0.8 (0.15)  **Gb:** 1.1 (0.14)  **Ga vs. Gb:** p=NS  Breast symptoms, days per cycle, mean (SE):  **Ga:** 0.9 (0.13)  **Gb:** 1.1 (0.18)  **Ga vs. Gb:** p=NS  **Quality of life:**  NR  **Patient satisfaction:**  NR  **Fertility:**  NR  **Time to conception:**  NR  **Additional interventions:**  NR | **Overall quality:**  Fair  **Risk of bias:**  Randomization:  Unclear  Allocation concealment:  Unclear  Selective reporting:  Low  Blinding patients/personnel:  Low  Blinding outcome assessment:  Low  Incomplete outcome reporting:  High/Low  Other:  **Low** |

**Table Notes:** a Intrauterine device (n=6), fibroids (n=2), and Von Willebrand’s disease (n=1); b Comparison of patients’ subjective assessment of menstrual blood loss (60/69 87%) provided perception data accurate enough for analysis.