**AUB KQ1 Evidence Table (Reference ID #1103)**

| **Study Description** | **Intervention(s)/ Comparator(s)** | **Patient Population** | **Baseline Measure(s)** | **Outcome Measure(s)** | **Overall Quality****Risk of Bias** |
| --- | --- | --- | --- | --- | --- |
| **Author:**Fraser et al., 1991**Country:**Australia**Enrollment** **period:** NR**Intervention** **setting:** NR**Funding:**Parke-Davis CompanySydney, Australia**Author industry relationship disclosures:**NR**Study Design:** RCT (cross-over)**Blinding:** None | **Interventiona:** Mefenamic acid, 500 mg every 6-8 hours from first sign of menses until 24 hours after usual duration of heavy bleeding for a maximum of 5 days;Naproxen, 500 mg at first onset of menses followed by 250 mg every 6-8 hours until 24 hours after usual duration of heavy bleeding for a maximum of 5 days**Comparator:** Mefenamic acid, 500 mg every 6-8 hours from first sign of menses until 24 hours after usual duration of heavy bleeding for a maximum of 5 days; Low dose combined oral contraceptive (ethinyl estradiol 30 µg and levonorgestrel 150 µg) daily for 21 out of 28 days**Groupsb:****G1:** Cycles 1 and 2: no treatment Cycles 3 and 4: mefenamic acid or naproxenCycles 5 and 6: no treatmentCycles 7 and 8: mefenamic acid or naproxen **G2:** Cycles 1 and 2: no treatment Cycles 3 and 4: mefenamic acid or combined monophasic oral contraceptive Cycles 5 and 6: no treatmentCycles 7 and 8: mefenamic acid or combined monophasic oral contraceptive **Ga:** Mefenamic acid**Gb:** Naproxen**Gc:** Combined oral contraceptive**Followup:**8 cycles | **Inclusion criteria:** * Menorrhagia

Regular periodsOvulatingNo hormonal therapy in the previous 3 months**Exclusion criteria:** Menorrhagia due to pelvic causesMenorrhagia due to systemic causes**N at enrollment:** **G1:** 15**G2:** 15**N at followup:** **G1:** 14**G2:** 12**Age:** NR**BMI:** NR **Parity:** NR **Race/ethnicity:** NR | **Bleeding:**MBL measured by alkaline hematin method in cycles 1 and 2, mean ml ± SD:**G1:** 131.1 ± 80.8**G2:** 101.0 ± 52.5 | **Bleeding:** MBL measured by alkaline hematin method during 2 mefenamic acid treatment cycles, mean ml ± SD:**G1:** 105.1 ± 88.6**G2:** 62.9 ± 27.7MBL % change from baseline during 2 mefenamic acid treatment cycles:**G1:** -20**G2:** -38**G1 vs. BL:** p=0.198**G2 vs. BL:** p=0.002MBL during 2 no treatment cycles 5 and 6, mean ml ± SD:**G1:** 131.9 ± 71.6**G2:** 90.9 ± 61.3MBL during 2 treatment cycles (G1: naproxen; G2: COC), mean ml ± SD:**Gb:** 115.6 ± 113.0**Gc:** 57.8 ± 34.8 MBL % change from baseline during 2 treatment cycles (G1: naproxen; G2: COC):**Gb:** -12**Gc:** -43**Gb vs. BL:** p=0.079**Gc vs. BL:** p<0.001MBL reduction during 2 treatment cycles with mefenamic acid compared to 2 treatment cycles with naproxen and COC: **Gb vs. Ga:** p=0.129 **Gc vs. Ga:** p=0.079Clinically significantc reduction in MBLduring 2 mefenamic acid treatment cycles, n (%):**G1:** 8/14 (57)**G2:** 10/12 (83)Clinically significantc reduction in MBLduring 2 treatment cycles, n (%):**Gb:** 9/14 (64)**Gc:** 9/12 (75)**Quality of life:**NR**Pain:**NR**Sexual function:**NR**Patient satisfaction:**NR**Fertility:**NR**Time to conception:**NR**Additional interventions:**NR | **Overall quality:**Poor**Risk of bias:** Randomization:UnclearAllocation concealment:UnclearSelective reporting:LowBlinding patients/personnel:HighBlinding outcome assessment:HighIncomplete outcome reporting:HighOther:Low |

**Table Notes**: a A third group, not included in this review, received mefenamic acid and danazol (n=15); b The order of treatment within each group was randomized; c Objective reduction of 20% between the mean of first two cycles and mean of each 2 treatment cycles.