**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 Company  Sydney, 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 naproxen  Cycles 5 and 6: no treatment  Cycles 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 treatment  Cycles 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 periods  Ovulating  No hormonal therapy in the previous 3 months  **Exclusion criteria:**  Menorrhagia due to pelvic causes  Menorrhagia 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 ± 27.7  MBL % change from baseline during 2 mefenamic acid treatment cycles:  **G1:** -20  **G2:** -38  **G1 vs. BL:** p=0.198  **G2 vs. BL:** p=0.002  MBL during 2 no treatment cycles 5 and 6, mean ml ± SD:  **G1:** 131.9 ± 71.6  **G2:** 90.9 ± 61.3  MBL 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<0.001  MBL 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=0.079  Clinically 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:  Unclear  Allocation concealment:  Unclear  Selective reporting:  Low  Blinding patients/personnel:  High  Blinding outcome assessment:  High  Incomplete outcome reporting:  High  Other:  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.