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REAL WORLD DATA OF 226 UK WOMEN TREATED WITH ULIPRISTAL ACETATE FOR SYMPTOMATIC UTERINE FIBROIDS: COMPARISON WITH TOTAL EU PREMYA STUDY POPULATION

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Context: This European PASS study with ESMYA (ulipristal acetate, UPA) characterised and described treatment with a 3-month course of UPA 5mg in a pre-operative setting.
Objective: Sub-analysis of the UK arm of the study to compare and contrast the safety, effectiveness, and Health Related QoL outcomes in a population treated according to standard UK clinical practice with outcomes in the total EU study population.
Methods: Women undergoing pre-operative treatment with UPA within the UK were followed up during UPA treatment and for up to 12 months after treatment discontinuation. Data was collected at every secondary care visit.
Patients: The UK enrolled 226 patients at 11 sites which constituted 15.3% of the total cohort (n=1473), which were enrolled at 73 sites in 10 EU countries.
Main Outcome Measures: Patient demographics and outcomes were recorded. These included assessment of benefits (perceived by both patients and clinicians), health related QoL and pain assessment, as well as whether surgery was performed and its timing in relation to the administered UPA.
Results: UK demographics were different compared to that of the EU study population. Mean BMI (29.7 v 26.0) and body weight (78.4 v 71.0 Kg) were higher in the UK population, as was the proportion of non-Caucasian participants (37.6% v 16.1%). Symptomatic improvement was seen in both analysis subsets with small differences in the overall pattern of improvement after one UPA course. Overall 571 (38.8%) patients underwent surgery which included 152 (72.7%) of UK patients and 419 (33.6%) patients from the rest of the European sites. Similar proportions of women completed the study in both cohorts with no indication of differences in safety outcomes.
Conclusions: The group recruited from the UK had different demographics to the whole participants which may explain the differences noted in treatment benefits. Differences in the rate and timing of surgical interventions may reflect the UK healthcare system (vs European models) rather than satisfaction with treatment. The women who did not have surgery may represent a self-selected group who are surgery-averse regardless of efficacy.

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