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COMBINED ORAL MEGESTROL ACETATE/ LEVONORGESTREL-INTRAUTERINE SYSTEM FOR ATYPICAL ENDOMETRIAL HYPERPLASIA: A SINGLE-CENTER PROSPECTIVE RANDOMIZED CONTROLLED PILOT STUDY

ORAL FEATURED POSTERS

Lecture Title:

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Objectives: To assess if addition of levonorgestrel-intrauterine system (LNG-IUS) to megestrol acetate (MA) could improve treatment outcomes for patients with atypical endometrial hyperplasia (AEH).

Methods: In this open-label randomized controlled pilot study, patients were recruited from the Obstetrics and Gynecology Hospital, Fudan University.Between June, 2017, and June, 2020, 180 AEH patients met inclusion criteria and were randomly assigned (1:1:1) to MA+LNG-IUS group (160mg oral MA daily with LNG-IUS), LNG-IUS group or MA group (160mg oral MA daily). Hysteroscopic pathological evaluation was performed every 3 months during the treatment duration. The primary outcome, time to complete response (CR), was time from treatment initiation to pathologic assessments without lesions. Efficacy and safety were assessed in patients who received treatment. ClinicalTrials.gov: NCT03241888.

Results: Median age was 33 years (range 19–44). 58 received MA, 59 received LNG-IUS and 54 received MA+LNG-IUS. At data cutoff of the analysis on January 31, 2021, median follow-up was 25.9 months (range, 2.8-43.5). CR time was significantly shorter with LNG-IUS compared with MA (median, 4.4 vs. 7.0 months; hazard ratio 1.53; 95% confidence interval, 1.05-2.25; p=0.028). No significant difference in CR time was found between MA+LNG-IUS group and MA group. LNG-IUS group had lower incidence of weight gain (p<0.001), abdominal pain (p=0.036), insomnia (p=0.005), edema face (p=0.003), night sweats (p=0.003) and nocturia (p=0.002) than MA group. MA+LNG-IUS group had higher incidence of vaginal hemorrhage (p=0.002) than MA group.

Conclusions: LNG-IUS significantly improved CR time compared with that for MA, with less adverse events, and might be an alternative treatment option for AEH patients.