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Short communication

PRESCRIPTION EVENT MONITORING STUDY TO ASSESS THE SAFETY PROFILE OF ORAL NATURAL MICRONIZED PROGESTERONE SUSTAINED RELEASE IN INDIA

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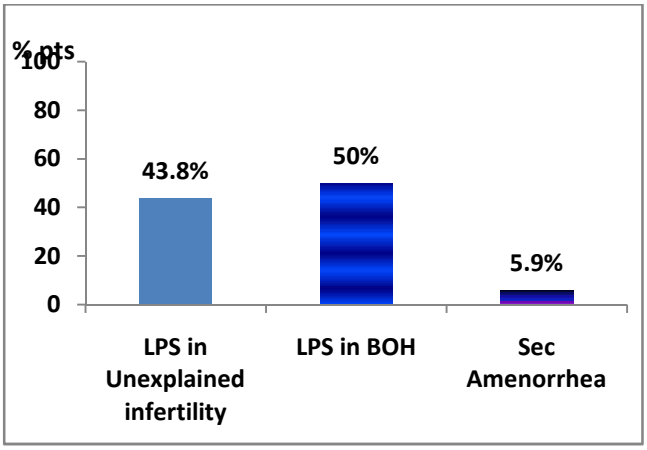
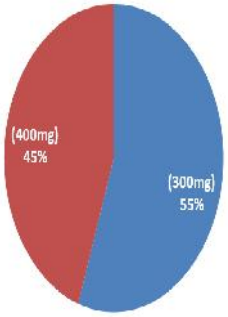
ABSTRACT

Background: Role of natural micronized progesterone (NMP) in various therapeutic conditions, including luteal phase correction and luteal phase support (LPS) has been very well highlighted[1, 2]. It offers better safety profile on long term administration with ancillary immunomodulatory and anti-inflammatory properties[3]. Oral NMP in the form of sustained release (SR) offers better patient compliance due to once a day dosage schedule[4]. This employs a novel matrix technology for the release of progesterone in small pulses into the systemic circulation over a period of 24 hours, thereby minimizing the hepatic metabolism related side effects including sedation or drowsiness. **Objective**: To study the safety profile of oral NMP SR (Dubagest SR), a PEM study was conducted in the outpatient settings in India. **Materials and methods**: PEM study is a method employed worldwide to provide useful safety information on the drug when prescribed in 'Real-life clinic settings'. Patients with bad obstetric history (BOH) or unexplained infertility were prescribed either 300 or 400 mg SR once a day following induction with Natural or Stimulated ART cycle for two months. Safety information related as 'Events' was captured on the Study questionnaire sheet provided to 35 doctors across India for five patients at each centre between March and May '13.**Results:** 153 patients completed the study with a mean of 27yrs& 55kgs. In infertility patients with BOH 87% patients had ≥ 2 abortions. The formulation was prescribed for Luteal Phase Support in Unexplained infertility (43.8%) or BOH (50%) and Secondary Amenorrhoea (5.9%). Oral NMP 300 mg SR was the most commonly prescribed formulation. The formulation was well tolerated with side effects including drowsiness (0.6%), hyperemesis (1.3%)& giddiness (0.6%) that were mild and transient. Two patients reported Spotting that disappeared on continued therapy and in other case probably related to reappearance of menses. **Conclusion**: Oral NMP SR is a clinically feasible option for LPS especially in BOH cases having Insignificant side effect profile for improved compliance.





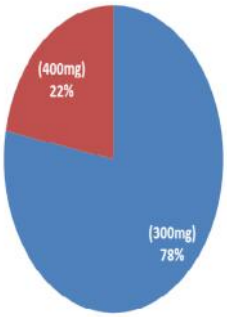


Fig. 2 - LPS in

Fig. 3 - LPS

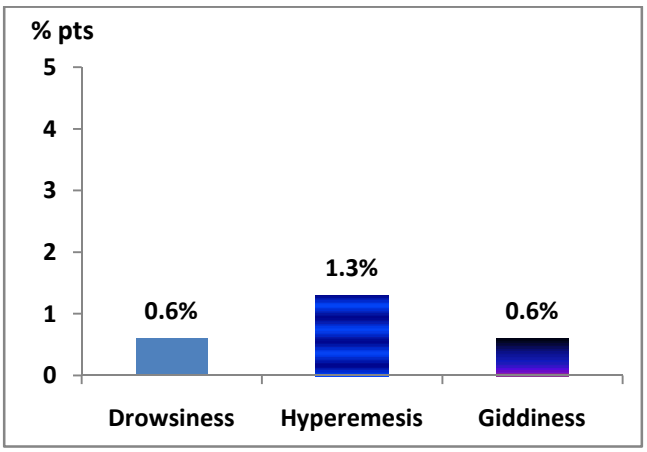


Fig. 3: Side effects with oral NMP SR

Conflict of Interest: Nil

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