

TO STUDY THE RECURRENCE OF ENDOMETRIOSIS AFTER TREATMENT WITH DIENOGEST VERSUS LEUPROLIDE FOLLOWING LAPAROSCOPIC SURGERY OF ENDOMETRIOSIS

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Background: Endometriosis results from an increased estrogen receptor (ER) activity in the ectopic endometrial implants outside uterus leading to cell proliferation, inflammation, adhesion formation and disease progression. Treatment options include medical, surgical, or their combination. Associated risk of recurrence after surgery is 21-25% at 2 years and 40- 50% at 5 years. Medical management is targeted to control pain and reduction of hormonally active endometriotic tissue. Short-term postoperative adjunctive hormonal therapy is helpful in decreasing recurrences.

Aim: To study reduction in recurrence of endometriosis and its symptomatology after laparoscopic surgery followed by treatment with Dienogest (19-nortestosterone derivative, strong affinity for progesterone receptors causing decidualization of the ectopic endometrial tissue) versus Leuprolide acetate (GnRH analog).

Methods: Prospective randomized trial included women between 18-40 years age, histopathologic confirmation of endometriosis following conservative laparoscopic surgery over a period of one year. Women with adnexal mass other than endometriosis, torsion, rupture, infertility, contraindications for hormonal treatment, refusal of consent were excluded. A total of 50 patients were randomized after laparoscopic cystectomy into 2 groups by computer-based random selection. Medical treatment commenced on next day of surgery. Study Group A received Dienogest at a dose of 2 mg once daily for three months. Study group B received Intramuscular Leuprolide 3.75 mg every 4th weekly x 3 injections. Follow up at 3 and 6 months for disease recurrence, VAS (Visual Analogue Scale) score for pain and CA-125 values as disease activity biomarker. Endometrioma of size ≥ 3 cm was considered as recurrence. Statistical analysis was conducted using IBM SPSS STATISTICS (version 22.0). The distribution of the continuous variables were tested with the Shapiro-Wilk test / Kolmogorov - Smirnov tests of Normality. For normally distributed data, the Student t-test was applied to compare mean endometrioma size and VAS score between two study groups. Skewed data was compared with Mann-Whitney test.

Results: Mean age (years) in group A and B 28.40 ± 6.3 and 30.20 ± 5.7 and mean age (years) at menarche in groups A and B 14.3 ± 1.2 and 13.4 ± 1.4 , respectively was comparable. indicating that onset of disease is early once menarche is attained. 92% presented with dysmenorrhoea, either alone or in association with dyspareunia or chronic pelvic pain. Disease severity categorization on laparoscopy as per ASRM classification was stage 3 in 52%, stage 4 in 32%, endometrioma size 6-10 cm in 56%, unilateral in 62%. On follow up of post operative adjunctive treatment, recurrence was seen in 11/50 (22%) (Group A=5, B=6), in stage 4 (45.4%) stage 3 (36.3%), at 6 month (10/11.) VAS score was significantly reduced in both groups A (p 0.0001 and 0.003), B (0.0001 and 0.002) as well as mean CA 125 (p=0.001 and 0.003) respectively.

CONCLUSION

Oral Dienogest is as effective as 4 weekly Leuprolide injection for prevention of recurrence, relieving pelvic pain after conservative surgery of endometriosis. Further research in a larger sample size and longer duration is need of the hour as no definitive cure is available till date.

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References: VPG M. ESHRE guideline: Endometriosis. Human Reproduction Open. 2022;2022(2).