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Topic : Adhesion Prevention

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Preliminary results of a comparative randomized study in adhesion prevention : second-look evaluation shows significant results of Prevadh adhesion barrier

Post-surgical adhesions are a universal phenomenon whatever the surgical discipline is. In myomectomy, postoperative adhesions occur with an incidence of over 60%. The clinical consequences of these adhesions are multiple and potentially serious: they are implicated in 20 to 40% of secondary sterility problems in women and constitute the second cause of infertility. The aim of this comparative randomized study is to investigate the efficacy and long-term outcomes of a continuous and hydrophilic resorbable film (PREVADH-Sofradim-Covidien France) in preventing postoperative adhesion formation.

From May 2006 to February 2008, fifty-two patients aged 34 years \pm 5 years, undergoing myomectomy by open surgery, were randomly allocated to receive either PREVADH film or Ringer Lactate solution, directly applied to the uterine scars. Only patients with intramural and subserosal myomas larger than 6 cm were included in this study. The incidence, severity and extent of postoperative adhesions to the uterine scars were assessed during a laparoscopic second-look performed between 10-20 weeks. Postoperative follow-up is organized at 1 month, 1 month after second-look then each year during 3 years.

34 patients (18 patients in the PREVADH group, 16 patients in the control group) underwent laparoscopic second-look at 105.1 days \pm 47.5. Nine (50%) patients in PREVADH group and 15 (93.7%) in Ringer Lactate group demonstrate adhesions ($p=0.005$). Thus, 36 uterine scars were protected in PREVADH group and 27 in control group exhibiting respectively 33,3% and 81.5% of adhesions ($p=0.0001$). Mean severity scores was 1.2 \pm 0.4 in PREVADH group versus 1.6 \pm 0.5 in control group. Mean extent score was 1.6 \pm 0.8 versus 2.3 \pm 0.8 respectively. No serious adverse event related to PREVADH or control group was reported.

Myomectomy operations frequently result in pelvic adhesions which may impair fertility. PREVADH is effective in reducing adhesion incidence, severity and extent of uterine adhesion after myomectomy, demonstrating the need for adhesion prevention. PREVADH film acts first as a barrier and prevents adhesion formation. Its resorption restores the plan of a natural split between the structures previously separated by this barrier. The results of this multicentre randomized study show that PREVADH provides an efficient protection against gynaecologic postoperative adhesions and may have a favourable impact on long-term complications.