



SESSION (5)

Hot Off The Press – Clinical trials in IBD that will change your post-op practice now!

PREVENT Study Data – Infliximab in the Post-Operative Crohn's Disease Environment

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Prevention of disease recurrence following ileocolic resection continues to be an important clinical challenge in the management of Crohn's disease (CD), with 1-year postoperative endoscopic recurrence rates of up to 78%. Various prophylactic therapies have been studied, including 5-aminosalicylic acid (5-ASA), antibiotics, and thiopurine antimetabolites, but studies have not conclusively demonstrated consistent reductions in both endoscopic and clinical recurrence. More recently, a small randomized, placebo-controlled trial of 24 patients demonstrated that the tumour necrosis factor- α (TNF- α) inhibitor infliximab reduced the risk of endoscopic recurrence in patients with CD following ileocolic recurrence: only 1 of 11 infliximab-treated patients had endoscopic disease recurrence at 1 year, compared with 11 of 13 placebo-treated patients. However, that study was too small to demonstrate a statistically significant difference in clinical recurrence. The Prospective, Multicenter, Randomized, Double-blind, Placebo-Controlled Trial Comparing REMICADE® (infliximab) and Placebo in the Prevention of Recurrence in Crohn's Disease Patients Undergoing Surgical Resection Who Are at an Increased Risk of Recurrence (PREVENT) study was designed to assess the effectiveness of infliximab in the prevention of combined endoscopic and clinical recurrence following ileocolonic resection in patients with CD at high risk of recurrence based on clinical criteria. Within 45 days of surgery, 297 patients were randomized to receive infusions of placebo or infliximab (5 mg/kg) every 8 weeks. Outcome was assessed at 76 weeks. Endoscopic recurrence (Rutgeerts i2 – i4) occurred in 31% of infliximab-treated patients, compared with 60% of placebo-treated patients ($P<0.001$). A trend towards reduced clinical recurrence in the infliximab-treated patients did not reach statistical significance (13% in infliximab-treated patients versus 20% in placebo-treated patients; $P=0.097$). This study confirmed the effectiveness of infliximab in the prevention of postoperative CD recurrence, but the impact on symptomatic clinical recurrence and endpoints, such as occurrence of disease complications or need for further surgery, have not yet been conclusively demonstrated.

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