Rayzon® matches morphine after laparotomy in women

Although opioids have traditionally been selected for the routine alleviation of post-operative pain, they are regrettably associated with numerous unwanted adverse effects such as respiratory depression, nausea and vomiting, somnolence and dizziness. These not only cause discomfort to the patient, but may even prolong recovery. The introduction of the non-specific, nonsteroidal, anti-inflammatory drugs (NSAIDs) advanced the alleviation of post-operative pain, but they were still associated with some unwanted side-effects including upper gastro-intestinal tract ulcers and impaired platelet function leading to an increased risk of post-operative bleeding.

More recently, the COX-2 specific inhibitors, such as RAYZON® (parecoxib sodium), have become firmly established in the treatment of inflammatory conditions, specifically pain following oral, gynaecological and orthopaedic surgery. One reason is that they are less likely to provoke the side-effects associated with non-specific NSAIDs.

In a multicentre study[1] conducted at 12 sites throughout the USA, the analgesic effect of RAYZON® was compared to morphine in the alleviation of pain following elective gynaecological laparotomy via standard transverse or lower mid-line incision. The laparotomies were carried out under general anaesthesia, and on recovery the women were allowed access to postoperative morphine delivered by standard patient-controlled analgesia, until the morning of the first day after surgery. This was to ensure the uniformity of treatment prior to the administration of the study drugs. Thereafter those women (n=264, average age 44.5 years) who reported a baseline pain intensity that was moderate to severe, were randomly allocated under double-blind conditions to receive either a single IM dose of RAYZON® 40 mg, morphine 6 mg, morphine 12 mg, or a reference placebo. Rescue analgesia was available to the women on request.

The analgesic response was assessed using standard efficacy measures at 0 hours, 30 minutes and specified hourly intervals thereafter for up to 12 hours, or until rescue medication was requested. In addition, the general safety was evaluated continuously, and a Global Evaluation of Study Medication was provided by the women at the conclusion of the study.

After rigorous statistical analysis of the study results, the authors concluded that RAYZON® demonstrated an analgesic effect which was superior to the lower dose morphine (6 mg) and comparable to the higher dose morphine (12 mg) at all assessment times. Furthermore, RAYZON® possessed a significantly longer duration of analgesic response versus both the 6 mg and 12 mg morphine ($p<0.05$). In terms of patient tolerance, most adverse reactions were mild to moderate in intensity, with little difference reported from the women receiving active analgesia. RAYZON® was particularly well tolerated, with a side-effect profile which was very similar to that of placebo. Some patients receiving morphine developed a low-grade fever.

Based on this study, the authors concluded that as a single dose of RAYZON® 40 mg IM provides pain relief equivalent to morphine 12 mg IM but with longer duration of action, RAYZON® could be considered as part of a multimodal strategy for pain alleviation following gynaecological laparotomy. Moreover, this would reduce the need for opioids such as morphine, with their associated side-effects.

Reference

1. *Malan T P, et al. Parecoxib sodium 40 mg IM is as effective as morphine 12 mg IM following gynecologic laparotomy. ESA, 2003. 10/RAY/03/04/JA*