

Summary attachment - study ended before 21 July 2013

EudraCT number: 2008-000791-24

Full title of the study: The effect of anti-inflammatory analgesics on pain after Hallux Valgus surgery; a prospective randomised study comparing a weak opioid and a Coxib.

Sponsor: Karolinska Institutet

Contact person: jan.jakobsson@ki.se

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Link to published article: https://journals.lww.com/anesthesia-analgesia/Fulltext/2010/08000/Pain_Management_After_Elective_Hallux_Valgus.45.aspx

Abstract from published article:

BACKGROUND: Pain is a common complaint after day surgery, and there is still a controversy surrounding the use of selective cyclooxygenase-2 (COX-2) inhibitors. In the present prospective, randomized, double-blind study we compared pain management with a selective (COX-2) inhibitor (etoricoxib) with pain management using sustained-release tramadol after elective hallux valgus surgery.

METHODS: One hundred ASA 1 to 2 female patients were randomized into 2 groups of 50 patients each; oral etoricoxib 120 mg × 1 × IV + 90 mg × 1 × day V–VII and oral tramadol sustained-release 100 mg × 2 × VII. Pain, pain relief, satisfaction with pain management, and need for rescue medication were evaluated during the first 7 postoperative days. A computed tomography scan evaluating bone healing was performed 12 weeks after surgery. A clinical evaluation of outcome (healing, mobility, and patient-assessed satisfaction) was performed 16 weeks after surgery.

RESULTS: Two patients withdrew before discharge from the hospital. Ninety-eight patients, 81 ASA 1 and 17 ASA 2 (82 nonsmokers and 14 smokers), mean age 49 years (19–65), weight 64 (47–83) kg, and height 167 (154–183) cm were evaluated. Overall pain was well managed, but the mean visual analog scale (VAS) was significantly lower among etoricoxib patients evaluated during the entire 7-day period studied (12.5 ± 8.3 vs. 17.3 ± 11 , $P < 0.05$). patient's grading of pain relief (92 ± 12 vs. 85 ± 15 , $P < 0.05$) and satisfaction with pain medication (47/49 vs. 39/49, $P < 0.05$) was higher among etoricoxib patients. Patients receiving tramadol reported significantly more side effects. Six patients, all in the tramadol group, discontinued the study because of side effects ($P < 0.05$). At 14-day follow-up 1 patient in the etoricoxib group and 5 patients in the tramadol group exhibited minor irritation in the wound area. The 12-week computed tomography scan showed good healing in 82 patients,

43 in the etoricoxib group, and 39 in the tramadol group. The study found ongoing healing in 11 patients, 4 in the etoricoxib group and 7 in the tramadol group. The 16-week patient-assessed Health Profile Quality of life revealed high patient satisfaction overall; 47 patients in each study group rated the outcome as satisfactory and the mean change in the patient-assessed quality of life VAS score was 6.2 and 2.6 for the etoricoxib and tramadol groups, respectively. Clinical follow-up at 16 weeks showed high functionality and no signs or symptoms of improper healing in any patient.

CONCLUSION: Etoricoxib was found to be more effective and associated with fewer side effects in comparison with tramadol sustained release as a component of multimodal analgesia after elective hallux valgus surgery. There were no signs of impaired wound or bone healing associated with the use of etoricoxib.

Sofie Possmark
Coordinator
Compliance & Data Office
Research Support Office
Karolinska Institutet
Sweden