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Title: Transdermal Fentanyl Delivery System vs Morphine IM: A Comparison of Analgesia After Major Orthopedic Surgery

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Introduction: Transdermal fentanyl (FTDS) provides relatively constant blood levels[1] and is efficacious treating patients following abdominal surgery[2]. The purpose of this study was to compare two strengths of FTDS to IM morphine for pain relief after major spine or reconstructive knee surgery.

Methods: Thirty-six ASA PS I-II patients scheduled for elective spine or reconstructive knee surgeries gave informed written consent for this IRB approved study. All patients were premedicated with 10 mg diazepam po. Prior to induction of general anesthesia, patches (40cm^2, 60cm^2 fentanyl or placebo) were placed on the patient's anterior chest wall or lower back and remained in place for up to 24 hours. Strength was allocated in a randomized, double-blind fashion Prior to incision, all patients received 5 μg/kg fentanyl IV. No more narcotics were administered during surgery. Anesthesia consisted of thiopental, muscle relaxant, and isoflurane as needed. Postoperatively, patients were monitored for up to 24 hrs or until "rescue" IM analgesia was required. When awake, patients were asked to rate pain and comfort and were offered IM injections every 6 hrs. The morphine group received IM-injections of morphine 150 μg/kg, while the patch groups received placebo. The patient and monitor independently judged overall pain management at the conclusion of the study.

Data was analyzed by Kruskal-Wallis tests with $p<0.05$ considered significant.

Results: There were no differences between groups in demographics or ASA status. There were no differences in assessment of sedation between the 3 groups. Two patients in the 60cm^2 group were removed from the study due to severe respiratory depression. Seven of 12 patients receiving IM morphine withdrew from the study due to pain while only 1 of 12 and 3 of 12 patients dropped out of the 40cm^2 and 60cm^2 fentanyl groups ($p<0.05$). Assessment of patient comfort postoperatively showed significantly less pain in the two fentanyl groups than in the morphine group. A significantly greater number of patients in the two FTDS groups slept overnight postoperatively. There were significant differences between morphine and fentanyl groups in both patient and observer assessment of overall postoperative pain management (see Figure). Between 12 and 24 hr postoperatively, 94% of the patients in the morphine group accepted IM injections when offered; in the 40cm^2 group 35% accepted injections, and only 21% of patients wearing 60cm^2 patches accepted injections ($p<0.5$).

Conclusion: Both transdermal fentanyl formulations provide analgesia significantly superior to this IM morphine regimen. Although we found no significant differences in quality of pain relief between the two FTDS groups, the only respiratory difficulties occurred in the 60cm^2 patch group. In summary, 40cm^2 transdermal fentanyl patches provide an acceptable, convenient and comfortable combination of analgesia and respiratory adequacy following major orthopedic procedures.

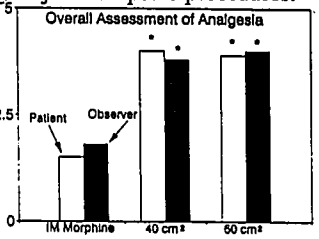

Figure 1.
Global assessment of Pain Relief after study
0 = Poor, 5 = Excellent
* = $p<0.01$ vs IM morphine

1. Pain. 37 (1989) p. 15-21
2. Pain. 40 (1990) p. 21-28

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TITLE: ROPIVACAINE DOES NOT IMPAIR WOUND HEALING IN PIGS

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Addition of vasoconstrictors to local anesthetics has been reported to impair wound healing.[1,2] Ropivacaine is the only local anesthetics that produces vasoconstriction when injected subcutaneously, except for cocaine.[3] This study was designed to evaluate whether ropivacaine can impair wound healing when injected subcutaneously in pigs.

After approval by our animal care committee (VMMC), anesthesia was induced with intraperitoneal thiopental in eight farm bred piglets (12.3-20.4 kg) and maintained with intravenous methohexital (0.36-0.62 mg·kg^{-1}·min^{-1}). Six sites were identified on the upper back (3 each side). Five sites were injected with 10 ml of either ropivacaine 0.25% plain (R), ropivacaine with epinephrine 5 μg/ml (R+E), bupivacaine 0.25% plain (B), bupivacaine with epinephrine 5 μg/ml (B+E), or saline (S). One site was not injected. Ten minutes later an incision was made completely through the dermis at each site. Wounds were closed with 3-0 Ethilon. Seven days later, the animals were euthanized, wounds were evaluated grossly by a blinded surgeon, then excised, evaluated histologically by a blinded pathologist, and tensile strengths were measured. Differences in tensile strengths were assessed by ANOVA.

There were no differences in the tensile strengths of healing wounds: R = 5.6 ± 2.4 (mean ± SD), R+E = 5.6 ± 3.2, B = 4.9 ± 2.6, B+E = 5.5 ± 2.6, S = 4.4 ± 1.9, and the uninjected site = 4.8 ± 2.5 kg·cm^{-2} ($p=.9$). All wounds exhibited normal healing on gross and microscopic examination.

Local anesthetics have been reported to inhibit the synthesis of collagen and glycosaminoglycans.[4] When epinephrine is added to local anesthetics, impaired wound healing has been reported. Thus, the vasoconstrictive properties of ropivacaine raise the possibility that this drug might impair wound healing. However, subcutaneous injection of ropivacaine does not impair wound healing - even when epinephrine is added to the local anesthetic solution. One limitation of this study is the fact that our animals were healthy and young with excellent healing abilities. Consequently, we can not exclude the possibility that infiltration of wounds might impair wound healing in certain groups of high risk patients (e.g., malnourished patients). However, this data suggests that infiltration of local anesthetic solutions containing vasoconstrictors should not increase the risk for postoperative dehiscence in healthy individuals.

References 1. ACTA Chir Scand 123:83-91, 1962 2. Br J Surg 64:892-903, 1977 3. Anesthesiology 71:69-74, 1989 4. J Surg Res 27:367-371, 1979