TITLE: ORAL TRANSMUCOSAL FENTANYL CITRATE (OTFC) FOR THE TREATMENT OF POSTOPERATIVE PAIN

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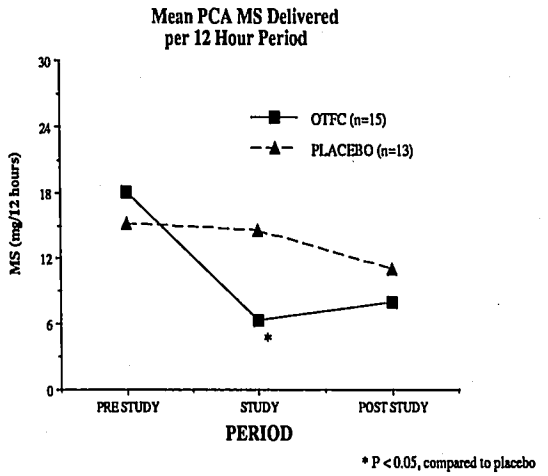
INTRODUCTION: Oral transmucosal fentanyl citrate (OTFC) has been used effectively as a premedicant for children and as a treatment for incident or breakthrough pain from terminal cancer. This prospective, randomized, placebo controlled, and double blind study was designed to determine if OTFC could provide analgesia to patients with acute pain after major surgery.

METHODS: The study was approved by our institutional human research committee. Oral and written informed consent to participate was obtained from thirty-eight ASA PS I-III patients undergoing either a total hip or total knee arthroplasty. The patients were studied prospectively and randomly allocated to receive either OTFC (7-10 μg/kg) or a placebo identical in appearance and taste to OTFC. General anesthesia was administered for surgery and all patients were started on patient controlled analgesia (PCA) with morphine (MS, 0.3 mg/ml). A PCA device was utilized to document the efficacy of transmucosally delivered fentanyl and to ensure patient comfort throughout the study. The PCA interval dose was adjusted to provide adequate analgesia as determined by the patient and the Acute Pain Service physician. The PCA lock-out period was 10 minutes which was not changed. No continuous infusions were utilized. On the morning following surgery, the most recent 12 hours of PCA data (MS mg/hr and attempts/hr) were recorded (PRE STUDY period). OTFC or placebo was administered at times 0, 4, and 8 hours during the 12 hour STUDY period resulting in 3 identical units being completely consumed, each over 15 minutes. Data was collected for the 12 hour treatment period and for the subsequent 12 hours (POST STUDY period). Treatment groups were compared for similarity and study variables were analyzed using appropriate statistical methods. $P<0.05$ was considered statistically significant.

RESULTS: 28 patients completed the study, 13 in the control group, 15 in the OTFC group. There was no statistically significant difference in the patients' age, gender, ASA classification or surgical procedure between groups. In addition, there was no difference between the groups in the number of PCA attempts or delivered dose of morphine via the PCA device during the PRE STUDY or POST STUDY periods. However, there was a significant decrease in the amount of morphine delivered to the OTFC group via the PCA device compared to the placebo group during the STUDY period ($p<0.05$). In addition, the number of mean PCA attempts by the OTFC group (9.67/12 hr) was lower than in the placebo group (25.31/12 hr) during the STUDY period, but did not reach statistical significance ($P=0.06$).



CONCLUSION: OTFC provided analgesia to patients with acute pain following major orthopedic surgery as documented by a significant decrease in PCA MS usage. Further investigation into the use of OTFC for the management of acute pain is warranted.

TITLE: LONG TERM EPIDURAL CATHETERS IN TERMINALLY ILL PATIENTS - A PROSPECTIVE STUDY OF COMPLICATIONS IN 129 PATIENTS

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Introduction: Epidural or spinal opioids are often the ultimate therapy in severe cancer pain. One of the limitation of this method is that the chronic catheter has to be inserted and cared for a long period of time with the adherent risk of catheter complications. Despite the widespread use there is limited published data on the complications of this technique in patients treated for weeks or months. The purpose of this study was to assess the relative safety of long term epidural catheters in terminally ill cancer patients.

Methods: After institutional approval informed consent was obtained from each patient. Catheter placement was uniform in all patients. An epidural catheter was inserted percutaneously via a Tuohyneedle (16 G) 3-4 cm into the epidural space and fixed 1 cm distally to the puncture site by a skin suture. An adhesive tape was rolled around the catheter. The puncture site was covered with povidone iodine unguent and renewed every two days. The catheter was taped over the back cranially and over the shoulder, where it ended with a bacterial filter. The injections (morphine or buprenorphine) were performed at home by family physicians, nurses and relatives or at the hospital by nurses according to our instructions.

Results: A total number of 154 catheters was inserted in 129 patients. 59 catheters were in place for 21 - 40 days, 38 for 41 - 60 days, 30 for 61 - 100 days and 27 catheters for more than 100 days (upper range 501 days). The combined data represent 10,424 patient days (28.6 years) of treatment. 108 patients were treated with 1 catheter, 17 with 2 and 4 patients with 3 catheters.

70.1 % of the patients were treated successfully until death or change to other methods (n=11) without any complication.

COMPLICATIONS

Infections		Malfunction		Malposition	
systemic	5	obstruction	2	dislocated	2
local	3	kinking	2	slipped	17
spinal	1	leakage	5	pulled out	4
		defect	5		

No life-threatening complication such as respiratory depression occurred in our series.

All infected catheters were removed and could be treated successfully by antibiotics. The patient with proven meningitis received a second catheter after successful treatment.

Conclusion: Percutaneously placed epidural catheters proved to be a successful regimen in terminally ill cancer patients even for long term pain treatment. The observed complication rate was lower than that reported in some smaller series with totally implanted systems.