Title: A PROSPECTIVE DOUBLE-BLIND STUDY OF CONTINUOUS THORACIC EPIDURAL ANALGESIA FOR THORACOTOMY PATIENTS

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Introduction: The use of epidurally administered analgesics for postoperative pain relief has gained widespread popularity in recent years. However, many of the reports concerning their effectiveness are anecdotal or uncontrolled. They also reveal a long list of practical problems associated with maintaining postoperative epidural analgesia and monitoring the patient receiving this type of pain control. Hoping to overcome some of these difficulties we undertook a prospective, randomized, double-blind study designed to document the effectiveness of continuously-administered epidural analgesics and to contrast our patients' comfort and complications when receiving continuously-administered epidural analgesics with parenterally administered analgesics.

Methods: Patients scheduled to undergo thoracotomy were randomized into five groups. Group 1: Epidural morphine 0.1 mg/ml. Group 2: Epidural bupivacaine 0.1%. Group 3: Epidural morphine 0.1 mg/ml and epidural bupivacaine 0.1%. Group 4: Epidural saline. Group 5: Epidural could be used intraoperatively but discontinued after surgery. All epidural catheters were placed preoperatively combining the lateral approach with the loss-of-resistance technique at the thoracic level corresponding to the middle dermatome crossed by the surgical incision. Epidural solutions administered with constant infusion pumps were started thirty minutes after induction of anesthesia at either 3 or 4 ml/hr based on the patients' height. Postoperatively, if a patient in one of the epidural groups had significant pain or agitation, the rate of epidural solution administration was increased in two successive one ml/hour increments. In all groups whenever a patient complained of significant pain a standard dose of morphine 0.1 mg/kg IM or 0.03 mg/kg IV was given. A standardized non-narcotic premedication and inhalational anesthetic technique was administered to all patients. The study covered the first postoperative seventy-two hours during which time pain was self-assessed every four hours (while awake) using a visual analogue pain scale (0 = no pain, 10 = most severe pain). Respiratory parameters including FEV_1, FVC, and MMEF were checked preoperatively and each day postoperatively. The patient's ability to cooperate with the care plan was assessed by his primary nurse every eight hours. Throughout the study, all complications were recorded.

Results: The patients in the five groups were comparable with respect to age, weight, height, operation, and preoperative smoking history. The average self-assessed pain scores for the five groups were: Group 1 = 3, Group 2 = 3.6, Group 3 = 0.4, Group 4 = 4.4, and Group 5 = 6.4. The lower pain score in Group 3 was statistically significant when compared to Group 1 ($p < .05$) and Groups 2, 4 & 5 ($p < .01$). The average amount of supplemental morphine requested by Group 3 during the first postoperative seventy-two hours (9 mg) was significantly ($p < .01$) lower than that requested by any other group (Group 1 = 47 mg, Group 2 = 87 mg, Group 4 = 104 mg, Group 5 = 120 mg.). There was no significant difference in the groups' ability to comply with postoperative respiratory care, reposition themselves, or self-ambulate postoperatively although there was a trend for patients in Group 1 to perform these tasks better on each postoperative day. Respiratory parameters measured postoperatively were significantly decreased ($p < .01$) in all groups when compared to their preoperative values. However, there was no statistical difference in the decreases experienced by the five groups, although the patients in Groups 4 and 5 tended to have the greatest decrease in FVC, FEV_1, and MMEF each day. Complications appeared to be evenly distributed between the groups. One patient in Group 1 had an episode of pruritis. Eight patients had self-limiting nausea or emesis (two patients each in Groups 1, 2, & 4 and one each in Groups 3 & 5). A drop in blood pressure to 70% of normal which responded to fluid administration was seen in two patients in Group 3 and one patient each in Groups 2 & 5. Eight patients developed atelectasis (two patients each in groups 1, 3, 4 & 5) and one patient developed pneumonia (Group 2). Foley catheters were routinely placed, so urinary retention was not evaluated. No patients developed significant respiratory depression and no complications were directly related to the placement or use of the thoracic epidural technique.

Discussion: In this double blind prospective study we found that the continuous epidural infusion of a relatively small dose of morphine in combination with bupivacaine was able to provide thoracotomy patients with greater comfort and pain relief than the continuous epidural infusion of morphine, bupivacaine, or saline alone, or a standardized parenteral narcotic regimen. Although patients in Group 3 had the best pain relief we were unable to find a significant improvement in their postoperative respiratory function when compared to the other groups. As a continuing study, we hope to more definitively address the idea that with less postoperative pain, there is a more rapid return of function leading to fewer respiratory complications. We believe the use of a continuous infusion promotes a more steady level of pain relief and avoids the need for bolus reinjections which are frequently associated with complications. Although the use of a continuous thoracic epidural may be associated with potential risks, we believe its use allows the administration of smaller doses of epidural narcotics thus lessening the potential of life-threatening respiratory depression while still providing excellent pain relief.