

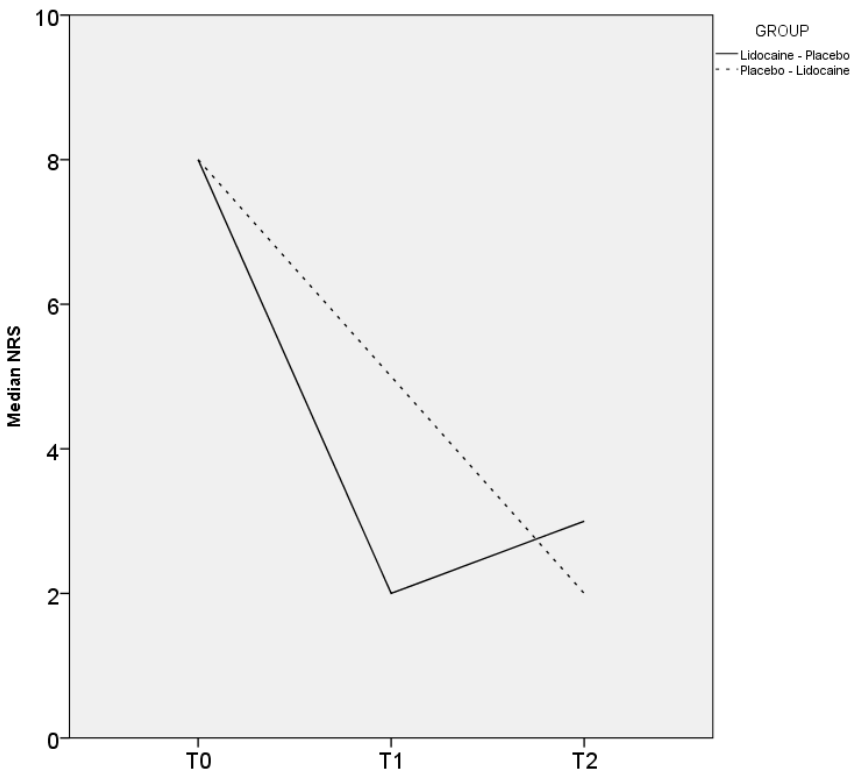
Effect of Infrapatellar Nerve Block on Chronic Anterior Knee Pain After Tibial Nailing: A Randomized Double-Blind Placebo-Controlled Study (INCOP)

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Purpose: Chronic knee pain is a common complaint after intramedullary nailing of tibia shaft fractures. Injury or entrapment of the infrapatellar nerve is a possible cause of this persisting postoperative knee pain. The purpose of this randomized, placebo-controlled, double-blind crossover trial was to compare changes in knee pain after an infrapatellar nerve block with lidocaine or placebo in patients with persistent knee pain after tibial nailing.

Methods: Between June 2000 and December 2013, 380 patients (age, 18-65 years) were treated with an intramedullary nail. These patients were sent a questionnaire regarding knee pain during eight activities (rest, walk, run, jump, kneel, squat, walk stairs, prolonged sitting with bent knees). Pain was rated using a numeric rating scale (NRS; 0 - 10). Criteria for inclusion in the trial were an NRS of 4-6 (moderate pain) during at least 3 out of 8 activities or an NRS of 7 or higher (severe pain) during 1 or more activities. 64 patients met these criteria, of whom 28 agreed to participate in the study and signed an informed consent. These patients were randomized to an infrapatellar nerve block with a subcutaneous injection of lidocaine or placebo after which they were supervised in performing the eight activities. Before and

PAPER ABSTRACTS



The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.

after these activities, pain was recorded using an NRS. Hereafter patients crossed over to the alternate group and pain scores were again recorded. Randomization of the treatment sequence was performed with use of a random-number generator. The allocated sequence was kept in sealed envelopes. Envelopes were prepared by a secretary who had no involvement in the trial. Upon each patient's enrollment into the study, the next consecutively numbered envelope was opened by an outpatient nurse. Two syringes were prepared, marked with number one or two according to the allocation, and checked by a doctor not involved in the trial. As both fluids were colorless and odorless, both patient and examiner remained unaware of which treatment was administered. The primary end point was the change in pain intensity during kneeling after each infrapatellar nerve block. Secondary outcomes were changes in pain intensity after each nerve block during rest, walking, running, jumping, squatting, climbing stairs, and sitting with flexed knees. Effects of lidocaine and placebo on NRS of all activities were analyzed using Mann-Whitney U.

Results: 28 patients aged 18-62 years (mean, 41 years \pm 13) signed an informed consent and were equally randomized. Mean follow-up was 89 (\pm 52) months. A significant reduction of the NRS for kneeling pain with an infrapatellar nerve block with lidocaine was found compared with placebo (median [range], -4 [-10 - +1] vs -1 [-11 - +8]; $P = 0.022$). There were no differences between the treatments for the NRS values for rest, walk, run, jump, squat, and prolonged sitting with bent knees.

Conclusion: Compared with placebo, an infrapatellar nerve block with lidocaine was more effective in reducing pain during kneeling in patients with chronic knee pain after tibial nailing. Data from the present study therefore support the contention that kneeling pain after tibial nailing is a peripheral nerve-related problem.