Int. J. Oral Maxillofac. Surg. 2014; 43: 422–427
http://dx.doi.org/10.1016/j.ijom.2013.11.010, available online at http://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

Clinical paper
Cleft Lip and Palate

Donor site analgesia after anterior iliac bone grafting in paediatric population: a prospective, triple-blind, randomized clinical trial

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Abstract. The aim of this study was to compare the efficacy of femoral nerve block with indwelling catheter-based multiple infiltrations of bupivacaine for postoperative pain management after iliac bone harvesting. Sixty paediatric patients undergoing iliac harvesting were randomized into three groups: group A, preoperative femoral nerve block; group B, multiple bolus infiltration of 0.5% bupivacaine via indwelling catheter at the donor site; group C, controls – single dose of 0.5% bupivacaine infiltration given subcutaneously. The primary outcome measure was postoperative pain intensity at rest and at function. The time to maximum pain score, time to ambulation, duration of analgesia, and length of hospital stay were also assessed. Group B patients had the best pain relief and return to function, however the duration of pain relief was longer in group A. Subjects in group A had concomitant motor blockade causing delayed ambulation. Group C showed the worst outcomes. Indwelling catheter-based infiltration of bupivacaine was the most efficient method for providing enhanced pain relief after iliac bone graft harvesting. There was no increase in operating time or hospital stay. Femoral nerve block provided the next best results, but had the significant disadvantage of motor nerve blockade.

Key words: three-in-one femoral nerve block; indwelling catheter; bupivacaine; iliac bone harvesting; donor site analgesia.

Accepted for publication 13 November 2013
Available online 27 December 2013

Autologous bone harvested from the ilium is currently the gold standard for cleft alveolar repair because of ease of access, the abundance of corticocancellous bone,[1] convenience of a two-team approach, and relative ease of harvesting.[2,3] However studies have reported drawbacks to iliac crest harvesting, including postoperative morbidity such as persistent pain, delayed ambulation, and prolonged hospitalization.[4] Of these factors, the patient is most concerned with postoperative pain; in most cases this pain is said to be worse than the pain experienced at the recipient surgical site. The use of alloplastic grafts as an

0901-5027/040422 + 06 $36.00/0

alternative poses the threat of increased infection, graft migration, rejection, and the added cost of the material. Autologous grafts have overcome these problems, but complications of donor site morbidity and the need for a second surgical site have resulted in a questioning of their use.[5]

The systemic administration of narcotics helps with pain relief, but has well-documented potential side effects such as nausea, vomiting, excessive sedation, and respiratory depression.[6] Studies have shown various strategies to reduce postoperative pain at the donor site, which include the administration of a single dose of bupivacaine at the donor site,[2] nerve blocks such as femoral nerve block and psoas sheet block,[7,8] epidural anaesthesia,[9] repeated bolus or continuous infusions of the local anaesthetic agent via an indwelling catheter,[10,11] and a change in operative technique.[12] There is a lack of randomized trials comparing the different means of local pain relief in paediatric patients undergoing iliac bone harvesting for the management of cleft alveolus.

The purpose of this study was to compare the efficacy of a single, preoperative 'three-in-one femoral nerve block'[7] versus an indwelling catheter-based analgesia of 0.5% bupivacaine with repeated rescue bolus infusions, against a control of single-dose infiltration of 0.5% bupivacaine, for postoperative pain management after anterior iliac grafting in cleft alveolus repair in the paediatric population.

Methods

Trial design

The study was approved as a prospective, triple-blind, randomized clinical trial by the institutional review board before patient enrolment. The study sample comprised paediatric patients (age range 8–12 years) requiring unilateral secondary alveolar bone grafting with bone from the anterior iliac crest between May and December 2010. Written informed consent was obtained for all the children recruited into the study, either from the parent or the guardian who accompanied the child.

The inclusion criteria were: age 8–12 years; unilateral alveolar cleft; patients who were American Society of Anesthesiology grade I (ASA I); no previous history of iliac bone harvest. The exclusion criteria were: patients other than ASA I; patients unwilling to be a part of the trial; bilateral alveolar cleft deformity; systemic diseases; cleft patients with associated craniofacial syndromes; patients taking medications that could affect the outcome; known allergy to local anaesthesia.

None of the patients were withdrawn during the course of the trial due to any detrimental complications or side effects. Characteristics of the study population are given in Table 1.

Table 1. Characteristics of the study population.

Study variable	Group A	Group B	Group C
Sample size, *n*	20	20	20
Age, mean ± SD, years	10.2 ± 1.6	9.4 ± 1.6	9.6 ± 1.7
Sex: male, *n* (%)	10 (50%)	8 (40%)	8 (40%)

SD, standard deviation.

Sample identification and randomization

Sixty patients were randomized into three groups based on a lots system. To eliminate patient and surgeon bias, all patients had an indwelling catheter at the donor site. Group A patients received a single preoperative dose of three-in-one femoral nerve block, followed postoperatively by placebo on request via the catheter. Group B patients received a bolus infusion (via the catheter) intraoperatively plus rescue boluses administered on patient request via the indwelling catheter. Group C patients constituted the control group, and these patients received a single dose of bupivacaine as a depot injection intraoperatively, followed by placebo via catheter on request. The trial drug used in the study was 0.5% bupivacaine and the placebo was normal saline. The patients, surgeon, and data analyst were unaware of the group allocation, hence this trial was triple-blind. All patients enrolled in this study received oral ibuprofen (15 mg/kg) every 8 h for 7 days postoperatively.

Procedure and data collection

All surgical procedures were carried out under general anaesthesia; fentanyl (2 mg/kg body weight) was the only analgesic agent administered at the time of induction. Postoperatively all patients received oral ibuprofen (15 mg/kg) every 8 h for 7 days. Preoperatively group A patients received a three-in-one femoral nerve block with 0.5% bupivacaine, performed by the anesthetist.[7,13] The nerve block technique was standardized based on studies that have demonstrated the most successful point of needle entry to be directly lateral (1–1.5 cm) to the femoral artery in the inguinal crease (Fig. 1). All patients had a 16-gauge epidural catheter (Perifix; B. Braun Melsungen AG, Melsungen, Germany) (Fig. 2) placed intraoperatively in the sub-periosteal plane[10,11] after the iliac bone harvest, verified to be in position visually (Fig. 3). The catheter was secured with plaster tape. A standardized dosage of 0.2–0.3 ml/kg body weight, with a maximum allowable dose of 2 mg/kg body weight, of 0.5% bupivacaine was administered via the indwelling catheter in group B patients; this was the same volume given for the three-in-one block. Group C patients (controls) received a single-dose depot infiltration of 2 ml of 0.5% bupivacaine subcutaneously after the bone harvest was completed.

Postoperative pain management

Patients in group B received indwelling catheter-based analgesia of 0.5% bupivacaine for rescue doses on request, in addition to the oral ibuprofen. Group A and group C received placebo administrations along with the oral ibuprofen. The rescue bolus was calculated at the same dosage of 0.2–0.3 ml/kg body weight.

Outcome assessment

Patients were transferred to the recovery room, and once conscious, the pain scores were noted. The primary outcome assessment was the subjective evaluation of the intensity of pain at rest and at function based on the Wong–Baker FACES rating scale.[14] Pain scores were recorded every hour during the first 6 h and every 6 h for the next 48 h. The functional outcomes were assessed by noting pain during ambulation and pain during leg lifting. The time to maximum pain score, time to first ambulation, duration of analgesia, and length of hospital stay were also recorded. The highest pain score and the time when it occurred were tabulated. The time and number of rescue bolus doses on patient request were also noted. The patients were hospitalized until they deemed it was comfortable for them to return home. The number of days of hospital stay was also noted.