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The efficacy of local anaesthetic for pain after iliac bone harvesting: A randomised controlled trial

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ABSTRACT

Introduction: Autogenous bone grafting is commonly used in reconstructive surgery but postoperative pain from the donor site can be severe, delaying early mobilisation and preventing discharge from hospital.

Method: An RCT of levobupivacaine infusion (16.25 mg/h for 24 h) of iliac crest wounds versus placebo. Postoperative pain was recorded immediately on returning to the ward, then at 1, 2, 3, 4, 5, 6 h, morning and evening on subsequent days until discharge, and at the 7-day clinic appointment. Mobility was recorded twice daily and at 7 days.

Results: Of 46 evaluable patients, 25 were randomised to levobupivacaine and 21 to placebo. Mean pain scores for (i) average pain from initial assessment to 6 h; (ii) 1 day in the morning; (iii) 1 day in the evening; (iv) at 2 days; and (v) follow-up were all statistically significant in favour of lower pain scores in the levobupivacaine group (p -values all <0.01). Comparison between the study groups for mobility found 6 patients unable to get out of bed in the placebo group and none in the local anaesthetic group at the initial assessment (Fisher's exact test p -value = 0.005), and 2 patients at 24 h. Patients in the local anaesthetic group were always more mobile and this was statistically significant even at 7 days for gait disturbance, limp, deviation of gait and unequalness of stride. There were no complications relating to the infusion system.

Conclusions: Local anaesthetic significantly reduced postoperative pain and improved mobility. We recommend that surgeons use a local anaesthetic infusion to improve the postoperative experience for their patients undergoing iliac crest grafting.

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1. Introduction

Autogenous grafting provides material for reconstruction that is free from any risk of infectivity^{1–3} but is not without other

potential complications. The ilium is frequently the site of choice for the harvesting of bone^{4,5} and several different surgical techniques have been developed with the aim of reducing the associated morbidity.^{3,6–8} Despite this, postoperative

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pain from the donor site can be severe, increasing the requirement for systemic analgesia, delaying early mobilisation and preventing discharge from hospital.^{9,10} Less commonly the donor site procedure may cause chronic pain that is more problematic than the primary surgical procedure itself.¹¹

Although, local anaesthetic infusion to the harvest site has been advocated as a safe and effective method of reducing pain^{9,12} the efficacy has not been studied in a controlled fashion and not all studies have demonstrated better pain control.¹³ The aim of our study was to use a randomised controlled trial to investigate whether the post-operative experience of patients following iliac bone harvesting could be improved by reducing the pain experienced. Our chosen model was anterior iliac crest bone harvesting for the reconstruction of the mandible and maxilla. The anterior iliac crest is regarded as the donor site of choice for oral and maxillofacial reconstructive surgery^{9,14,15} as it provides access to a large quantity of donor bone with the patient in a supine position such that simultaneous operating at hip and the head and neck recipient site may occur, therefore reducing the operative and anaesthesia time.⁶ It is possible that the efficacy of a local anaesthetic infusion could be impaired when a drain is placed to the same site as this may lead to loss of the local anaesthetic solution. However, the requirement for a drain may be essential in some cases and so we elected to use a vacuum drain for all patients in this study.

Our hypothesis was that by using a continuous administration of local anaesthetic for 24 h via a catheter to the wound, patients would wake up pain free and experience less postoperative pain, promoting earlier mobilisation and discharge. Our primary efficacy variable was postoperative pain intensity and our secondary outcomes of interest were mobility, time to hospital discharge, and any donor site complications. Bupivacaine is widely used as a long acting local anaesthetic agent in both surgery and obstetrics and generally has a good safety record although rarely its use has resulted in fatal cardiotoxicity, usually after accidental intravascular injection. We used levobupivacaine 2.5 mg/ml, the single enantiomer version of bupivacaine, because it has a long duration of action and clinically equivalent anaesthetic potency to bupivacaine but with an improved cardiovascular and neurotoxicity safety profile.¹⁶ Ropivacaine also has an equivalent efficacy to bupivacaine but with less cardiotoxicity.¹⁷ All patients were given systemic analgesia according to our usual clinical practice.

2. Method

All patients scheduled for anterior iliac crest bone harvesting for reconstruction of the mandible or maxilla or both, who fulfilled the inclusion criteria were invited by two of the authors (PC and RO) to participate in this two-armed double blind randomised controlled trial. Ethical Committee approval was obtained. All patients were undergoing alveolar bone augmentation to facilitate the subsequent placement of oral implants. We calculated that 23 patients in each group would be required to detect a difference in means of 2.00 (the difference between the control group mean pain score of 7.00 and the local anaesthetic group mean pain score of 5.00) assuming that the common standard deviation was 2.00 using an independent

sample t-test with a 0.05 two-sided significance level. The statistical power of the study was 90%. We recruited 53 patients to provide 46 evaluable patients and undertook the study at Central Manchester and Manchester Children's University Hospitals NHS Trust from November 2004 to November 2006.

2.1. Inclusion and exclusion criteria

Patients were considered eligible for study inclusion if they were male or female, aged 18–75 years, ASA I or II, able to understand and co-operate with the requirements of the protocol and able and willing to exercise an appropriate written informed consent. Patients were excluded from participating in the study if they had a known hypersensitivity or allergy to bupivacaine or levobupivacaine or had a history of previous surgery or injury to the ileum.

2.2. Surgical procedure

Donor site and recipient site surgical procedures were standardised as far as possible and prophylactic antibiotics were administered to all patients. At the donor site, the skin incision was lateral and parallel to the iliac crest followed by dissection down through subcutaneous fat to the muscular aponeurosis. An oblique incision was made along the external oblique aponeurosis, starting 2 cm behind the anterior superior iliac spine, down onto the ilium. A cortico-cancellous block was removed from the medial plate using an electric saw and osteotomes. Cancellous chips were taken with a gouge. The volume of block and chips was measured by displacement of saline in a measuring syringe. In all patients a vacuum drain was placed deep against the medial plate and taken through the skin lateral to the incision. The aponeurosis was closed and an epidural cannula (16 g clear catheter Epidural Minipack, Portex Ltd. UK) placed into the wound superficial to the periosteum inserted through a separate skin puncture (Fig. 1).

The intraoral recipient surgical site was infiltrated with 5 ml bupivacaine 0.25% with 1:200,000 epinephrine prior to incisions being made. All surgery was undertaken by two of the authors (PC and RO). All patients received regular postoperative systemic analgesia with ibuprofen 400 mg 4–6 h

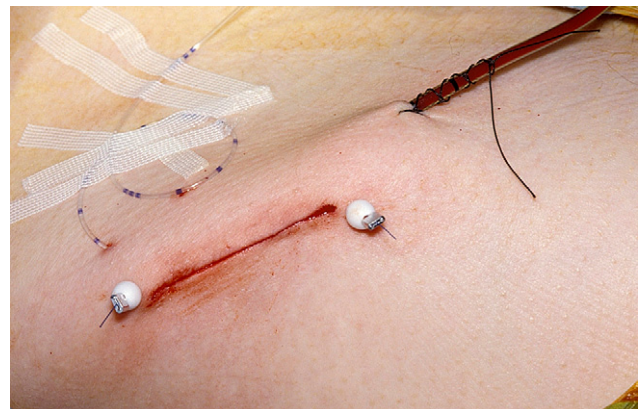


Fig. 1 – Photograph to show closed iliac crest wound closed with drain and local anaesthetic infusion cannula.

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