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CONTINUOUS INFUSION OF LOCAL ANESTHETIC AT ILIAC CREST BONE-GRAFT SITES FOR POSTOPERATIVE PAIN RELIEF

A RANDOMIZED, DOUBLE-BLIND STUDY

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Background: Autologous bone graft is the so-called gold standard for reconstruction of bone defects and nonunions. The most frequent complication is donor site pain. The iliac crest is a common source for autologous bone graft. The purpose of this study was to determine whether a continuous infusion of 0.5% bupivacaine into the iliac crest harvest site provides pain relief that is superior to the relief provided by systemic narcotic pain medication alone in patients undergoing reconstructive orthopaedic trauma procedures.

Methods: A prospective, double-blind randomized study of patients over eighteen years of age who were undergoing harvesting of iliac crest bone graft was conducted. The patients were randomized to the treatment arm (bupivacaine infusion pump) or the placebo arm. Postoperatively, all study patients received morphine sulfate with use of a patient-controlled analgesia pump. The patients recorded the pain at the donor and recipient sites with use of a scale ranging from 0 to 10. The use of systemic narcotic medication was recorded. Independent-samples t tests were used to assess differences in perceived pain relief between the treatment and control groups at zero, eight, sixteen, twenty-four, thirty-two, forty, and forty-eight hours after surgery. Pain was also assessed at two and six weeks postoperatively.

Results: Sixty patients were enrolled. Across all data points, except pain at the recipient site at twenty-four hours, no significant differences in the perception of pain were found between the bupivacaine group and the placebo group. On the average, patients in the treatment group reported more pain than those in the control group. No significant difference was found between the two groups with regard to the amount of narcotic medication used.

Conclusions: No difference in perceived pain was found between the groups. The results of this small, unstratified study indicate that continuous infusion of bupivacaine at iliac crest bone-graft sites during the postoperative period is not an effective pain-control measure in hospitalized patients receiving systemic narcotic medication.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

The use of autologous bone graft is the preferred method to treat osseous defects following trauma and in reconstructive orthopaedic surgery. The iliac crest is an easily accessed source for the autologous bone graft. Harvesting from the iliac crest is common, but is not without complications¹. Acute and chronic pain, sensory loss, he-

matoma, seroma, wound breakdown, contour defect, hernia through the donor site, gait disturbance, instability of the sacroiliac joints, fracture, dynamic ileus, and ureteral injury have been described as a result of iliac crest bone-grafting procedures. The most common complication is pain at the donor site, which is often more severe than pain at the surgical site¹⁻⁴.

Postoperative pain management is an important concern in the care of patients managed with an iliac crest bone graft. Adequate pain control has been shown to increase



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mobility³, potentially decreasing the risk of deep venous thrombosis. Patient satisfaction is also increased with control of postoperative pain, promoting quicker recovery⁵.

Narcotics and other systemic drugs can provide analgesia, but they often have side effects, such as respiratory depression, excessive sedation, nausea, and vomiting. Regional anesthesia with local anesthetic reduces the need for systemic medications but requires painful injection and repeated dosing. Local infiltration of a surgical incision with an anesthetic agent has been shown to provide adequate analgesia^{2,3,6,7}. Techniques include bathing the incision with local anesthetic prior to closure (providing a limited duration of pain relief), repeated injections into the wound (painful, with an increased risk of wound infection, and time-consuming), and placement of an epidural catheter into the wound to allow the delivery of repeated boluses of local anesthetic^{2,3,6,7}. The use of continuous local anesthetic infusion at surgical sites has grown in recent years with the introduction of prepackaged infusion devices in the orthopaedic marketplace. This technique allows for bathing of the surgical site with anesthetic agents without the need for repeat injections and is self-delivering, avoiding the need for repeated use of a bolus.

There have been numerous articles regarding installation of local anesthetic into the surgical site. The technique has ranged from local infiltration at the time of surgery⁸, to intermittent administration of a bolus through an indwelling catheter^{2,3,6}, to continuous infiltration⁷. To our knowledge, no double-blind, randomized, controlled study has been done to evaluate the efficacy of continuous bupivacaine infusion in decreasing postoperative pain and disability in the acute postoperative period in patients managed with harvesting of an iliac crest bone graft.

The purpose of this study was to determine whether a continuous infusion of 0.5% bupivacaine into the iliac crest harvest site provides pain relief that is superior to the relief provided by the use of systemic narcotic pain medication alone in patients undergoing reconstructive orthopaedic trauma procedures.

Materials and Methods

The institutional review boards of both participating institutions approved the study prior to the enrollment of any subjects. The study was approved as a randomized, double-blind, prospective, placebo-controlled study. All patients presenting to the orthopaedic service at two level-I trauma centers who were over eighteen years of age and undergoing harvesting of an iliac crest bone graft as part of the treatment for an isolated extremity injury or reconstruction were eligible to participate in the study. The inclusion criteria were (1) the ability to provide written, informed consent; (2) no contraindication to the use of morphine, meperidine, or hydromorphone; (3) the ability to use a patient-controlled analgesic device; and (4) normal renal and hepatic function, as demonstrated on routine preoperative laboratory tests. Normal renal function was defined by a blood urea nitrogen

level of <25 mg/dL and a serum creatinine level of <1.5 mg/dL. Normal hepatic function was defined as an aspartate aminotransferase level of <36 IU/L, an alanine aminotransferase level of <40 IU/L, and a total serum bilirubin level of <1.2 mg/dL. Patients who did not meet these criteria or had known allergies or sensitivities to bupivacaine or latex and those who had a documented history of renal or hepatic disease were excluded. Individuals who met the inclusion criteria were randomized to receive a continuous infusion of either 0.5% bupivacaine (the treatment group) or 0.9% normal saline solution (the control group). A random-number generator was utilized to generate the treatment assignment. Group assignments were sealed in sequentially numbered identical envelopes. An anesthesia provider or circulating nurse was responsible for opening the sealed envelope and dispensing the bupivacaine or saline solution. Both the patient and the surgeon were blinded as to the contents placed in the pump.

The pain-control infusion pump in this study was provided by Sgarlato Labs (Campbell, California). It consists of a simple assembly of components already used in medical devices. A spring is mounted on a syringe plunger and is capped by an outer shell. Medical-grade polyvinyl chloride tubing is connected to the syringe. A microglass cannula is placed in the end of the polyvinyl chloride tubing exiting the connector, and a catheter is connected to the end of the polyvinyl chloride tubing. When medication is injected into the injection port, it flows into the syringe, pushing the plunger against the spring. As the syringe reservoir is filled, the spring produces more pressure on the plunger, providing pressure on the medication fluid. The medication then flows through the microglass cannula, which controls the rate of flow at 2 mL/hr. Because the device works on mechanical pressure through a flow restrictor, there is no way to change the rate of infusion unless the microglass cannula is changed; however, this is not possible with the pump utilized in this study.

Patients underwent harvest of the iliac bone graft with use of a standardized trap-door technique. The iliac crest was osteotomized and hinged back on the inner table cortex allowing cancellous bone graft to be obtained from between the inner and outer tables of the iliac wing. The length of the osteotomy was recorded in centimeters. As the iliac crest site was closed, an epidural catheter connected to a pain-control infusion pump was placed into the wound along the outer table of the iliac crest over the periosteum. The pain-control infusion pump was loaded with either 100 mL of 0.5% bupivacaine or 100 mL of 0.9% normal saline solution.

All patients participating in the study initially received morphine sulfate administered with a standardized postoperative patient-controlled anesthesia device. The initial patient-controlled anesthesia orders called for a bolus of 1 mg of morphine sulfate with a lock-out rate of ten minutes. The patient-controlled anesthesia device was then adjusted or discontinued according to the clinical judgment of the treating physician on the basis of the pain control in the patient. The amount of pain medication the patient used was recorded.

TABLE I Demographic Data According to Study Group

	Control Group	Treatment Group	P Value
Males	17	18	
Females	13	10	0.373
Age* (yr)	39.6 (13.3)	41.1 (12.2)	0.673
Weight* (kg)	89.8 (21.7)	77.2 (17.4)	0.02†
Graft volume* (cc)	25.6 (10.5)	23.2 (11.3)	0.183
Trap-door size* (cm)	3.76 (1.1)	3.7 (0.96)	0.869

*The values are given as the mean with the standard deviation in parentheses. †The difference was significant at alpha = 0.05.

Patients recorded the pain for both the donor and recipient sites on a scale of 0 to 10, with use of a standardized visual analogue pain scale⁹. Study participants were asked to rate the pain initially in the recovery room and then every eight hours for the first forty-eight hours after surgery. Additional pain evaluations were performed at two weeks and six weeks postoperatively.

A power analysis, performed with use of PASS software (NCSS, Kaysville, Utah), indicated that a total of sixty subjects, with thirty patients in each group, would be needed to achieve power equal to 0.80 with an alpha of 0.05. The power analysis calculation was based on the assumption of an estimated mean pain score of 4 in the treatment group and 7 in the placebo group on the 10-point scale. It was thought that this difference would be clinically important. An estimated standard deviation of 4 was used. To determine whether there were systematic differences in either the demographic or surgical variables, chi square and t tests were conducted. When the data were not normally distributed, the Mann-Whitney test statistic was applied.

Results

Sixty patients were enrolled in the study, and fifty-eight had complete data sets. There were thirty-five male and twenty-three female patients. The average age of the patients was forty years. There were no significant differences between the groups with respect to age ($t = -0.425$, $p = 0.673$) or sex (chi square = 0.351, $p = 0.373$). The average weight of the patients was 89.8 kg in the control group and 77.2 kg in the treatment group. This difference in weight was significant ($t =$

2.394, $p = 0.02$). The anterior iliac crest was used in fifty-four patients, and the posterior iliac crest was used in four patients. One of the posterior iliac crest grafts was randomized to the control group, and the remaining three were randomized to the treatment group. To ensure equivalence of groups, we compared anterior and posterior harvest sites to determine whether there was a difference. No significant differences between these groups were noted with respect to demographic data, pain scores, or medication usage; thus, these groups were combined. The average size of the iliac crest osteotomy was 4 cm (range, 1.5 to 6.5 cm), and the average volume of graft was 24 cc (range, 3 to 60 cc). There were no significant differences between groups for either trap-door size ($t = 0.165$, $p = 0.869$) or graft volume ($z = -1.331$, $p = 0.183$). There were two infections in the treatment group and one hematoma in the control group, with all occurring at the donor sites. The demographic data on the patients in the control and treatment groups are summarized in Table I.

The recipient sites included the femur (eleven patients), tibia (twenty-seven), foot and ankle (seven), humerus (eight), forearm (four), and clavicle (one). The recipient sites according to the control and treatment groups are summarized in Table II. While the numbers related to each recipient site were too small for statistical analysis, we attempted to measure the effect of this variable by grouping recipient sites on the basis of region. Using this approach, we categorized the sites into upper extremity and lower extremity to examine differences by region. There were thirteen subjects in the upper-extremity group and forty-five subjects in the lower-extremity group. Mann-Whitney tests were used to analyze differences in pain

TABLE II Recipient Sites According to Study Group

Recipient Site	Control Group (no. of patients)	Treatment Group (no. of patients)	Total
Femur	8	3	11
Tibia	13	14	27
Foot and ankle	2	5	7
Humerus	5	3	8
Forearm	2	2	4
Clavicle	0	1	1

TABLE III Differences with Regard to In-Hospital Pain, Duration of Patient-Controlled Analgesia, and Amount of Pain Medication Delivered

	Control Group*	Treatment Group*	Statistic	P Value
Pain score at donor site	3.98 (2.37)	4.17 (2.32)	T = -0.304	0.762
Pain score at recipient site	4.93 (2.20)	5.65 (1.94)	T = -1.311	0.195
Duration of patient-controlled analgesia (hr)	40.9 (12.81)	45.9 (16.02)	T = -1.28	0.206
Morphine sulfate during first 24 hr (mg)	40.8 (48.43)	48.9 (35.76)	Z = -1.586	0.113
Morphine sulfate during second 24 hr (mg)	30.1 (38.91)	38.9 (35.86)	Z = -1.457	0.145

*The values are given as the mean with the standard deviation in parentheses.

at the recipient site at each time-point. No significant differences in pain at the recipient site according to region were found at any time-point. The number of subjects was not sufficient to analyze the individual groups by treatment. However, chi-square analysis indicated that there was no association between extremity region and treatment group (chi square = 0.030, $p = 1.0$), suggesting that the randomization process was sufficient, minimizing an unforeseen effect based on this variable.

Independent-samples *t* tests were used to assess whether there were differences between the treatment and control groups with regard to the average in-hospital pain and the average duration of time that the patient-controlled analgesia pump was used (Table III). The average in-hospital pain score for the donor site was 3.98 for the control group and 4.17 for the treatment group; the difference was not significant ($t = -0.304$, $p = 0.762$). The average in-hospital pain score for the recipient site was 4.93 for the control group and 5.65 for the treatment group; the difference was also not significant ($t = -1.311$, $p = 0.195$). For the treatment group, the average time from surgery to discontinuation of the patient-controlled anesthesia pump was forty-six hours. For the control group, the average time from surgery to discontinuation of the patient-controlled anesthesia

pump was forty-one hours; the difference was not significant ($t = -1.280$, $p = 0.206$).

Additionally, independent-samples *t* tests were used to assess whether there were differences in perceived pain relief between the treatment and control groups across all data collection points (Tables IV and V). With the exception of pain reported at the recipient site at twenty-four hours, no significant differences in the perception of pain were found between the treatment and control groups. Unexpectedly, the average pain score reported at the recipient site at twenty-four hours was significantly higher in the treatment group (6.18) than in the control group (4.60) ($t = -2.315$, $p = 0.025$). In general, patients in the treatment group consistently reported more pain than those in the control group. To further evaluate this phenomenon, a correlational analysis was conducted to examine the relationship between pain at the donor site and the recipient site. For all time-points, significant, moderately positive associations between donor site and recipient site pain were found ($p < 0.01$ for all). Patients in the treatment group also used more pain medication in the first twenty-four hours (an average of 49 mg of morphine sulfate) than those in the control group (an average of 41 mg of morphine sulfate) as well as in the second twenty-four hours (an average of 39 mg compared with an

TABLE IV Differences in Donor Site Pain by Treatment Group

Time	Pain Level*		T Value	P Value
	Control Group	Treatment Group		
0 hr	4.84 (3.40)	5.21 (3.32)	-0.418	0.678
8 hr	3.89 (3.09)	3.85 (3.18)	0.043	0.966
16 hr	4.36 (2.74)	4.04 (2.89)	0.422	0.675
24 hr	3.67 (2.45)	4.28 (2.81)	0.422	0.398
32 hr	3.88 (2.94)	3.89 (2.31)	-0.006	0.995
40 hr	3.84 (2.54)	3.76 (2.61)	0.115	0.909
48 hr	3.64 (2.46)	3.98 (2.87)	-0.454	0.652
2 wk	2.86 (2.16)	3.44 (2.48)	-0.87	0.389
6 wk	1.36 (1.90)	1.42 (2.43)	-0.102	0.919

*The values are given as the mean, with the standard deviation in parentheses.

TABLE V Differences in Recipient Site Pain by Treatment Group

Time	Pain Level*		T Value	P Value†
	Control Group	Treatment Group		
0 hr	6.33 (3.25)	7.23 (2.72)	-1.09	0.281
8 hr	5.23 (3.29)	5.56 (2.88)	-0.388	0.700
16 hr	5.72 (3.01)	5.72 (2.92)	0	NC
24 hr	4.60 (2.45)	6.18 (2.56)	-2.315	0.025*
32 hr	4.61 (2.90)	5.48 (2.39)	-1.188	0.240
40 hr	4.35 (2.72)	4.83 (2.81)	-0.64	0.525
48 hr	4.02 (2.56)	4.52 (2.71)	-0.665	0.509
2 wk	2.66 (2.18)	3.72 (3.09)	-1.358	0.175
6 wk	2.11 (2.32)	2.44 (2.59)	-0.437	0.664

*The values are given as the mean with the standard deviation in parentheses. †The difference was significant at alpha = 0.05. NC = not calculated because means were the same.

average of 30 mg in the control group). These differences were not significant for either the first twenty-four hours ($z = -1.586$, $p = 0.113$) or the second twenty-four hours ($z = -1.457$, $p = 0.145$) (Table III). However, when the use of morphine sulfate was analyzed for the forty-eight-hour study period and adjusted for median weight, the median amount of morphine sulfate used was 0.49 mL/kg in the control group and 1.00 mL/kg in the treatment group; the difference was significant ($z = -1.982$, $p = 0.047$).

Discussion

The results failed to prove the hypothesis in this setting. The pain-control infusion pump provided no additional pain relief to the patient as evidenced by the lack of decrease in narcotic use and no difference in the patient perception of pain between the control and treatment groups. The major strength of the study is its double-blind, randomized design. Statistical analysis demonstrated the validity of the randomization with similar demographic data for both the treatment and the control arm. Other strengths included the use of a validated pain scale and documented recording of narcotic use to measure the response of the patient to pain. Study limitations include the variation in the graft harvest site, the degree and variation in recipient sites, the size of the trap-door osteotomy, and the variability in narcotic dosages postoperatively.

In terms of the variation of the graft harvest site and the recipient sites, these are certainly uncontrolled variables. Given a larger sample size, these variables could have been stratified and randomized accordingly. However, despite these limitations, careful statistical analysis demonstrated no difference with regard to trap-door size or to recipient sites when grouped by region.

With regard to the trap-door osteotomy, the surgeon pool was limited to five surgeons who were trained and familiar with the osteotomy technique. While clearly this leads to increased variability, it also lends itself to the reality of

bone graft harvesting performed by a wide field of surgeons. Despite this factor, statistical analyses revealed no difference between the treatment and control groups with regard to trap-door size and graft harvest volume, suggesting that only differences in specific technique may have been an uncontrolled variable.

The other primary difficulty encountered was the standardization of the postoperative regimen for pain management. Despite the use of standardized postoperative order sets, individual variation in narcotic requirements was frequently encountered and required adjustment of the patient-controlled analgesia administration. This was most likely related to variation in the graft recipient site and the associated pain management requirements for each specific site. This potential weakness was minimized by the randomized study design and the power analysis. The statistical analyses, while not sensitive with regard to adjustment in the dosing parameters, demonstrated no difference between groups in total narcotic usage. Contrary to this finding, however, is the reported increased use of pain medication when adjusted for weight. This phenomenon was recognized in the treatment group. This was not completely surprising as the group as a whole had more pain, and with more pain one would expect a greater degree of narcotic usage.

Another weakness in the study was the potential to include patients with histories of substance abuse, smoking, chronic pain disorder, and psychiatric illness. These conditions can potentially alter the perception of pain and, in certain conditions, can blunt the response to systemically administered narcotics. While patients with these conditions were not specifically excluded from participation in the study, several safeguards were in place to minimize the effect of these conditions or exclude participants with active problems from the study. Patients unable to comply with the use of a patient-controlled analgesia device were excluded at the discretion of the investigator. This prevented the participation of patients with obvious psychosis or intoxication. The

laboratory screening process and exclusion criteria were relatively stringent; patients with considerable substance abuse issues were eliminated when elevated liver enzymes were present. While it remains impossible to control for all of these variables, this potential for weakness in study design would have been further mitigated by the randomization process.

Although several graft-site complications occurred, their frequency was not unexpected and was in line with results reported in the literature¹⁻⁴. Thus, these complications cannot be directly attributed to the pain-control infusion pump.

Despite the noted limitations of this study, its power was sufficient to demonstrate a significant and clinically important difference. However, if a smaller difference between groups is potentially meaningful clinically, then this protocol lacked adequate power to detect it. The most likely reason that there was no difference in perceived pain between the groups is the use of systemic narcotics in the form of morphine administered by patient-controlled analgesia.

In this study, the recipient bone-graft site was not treated with local anesthetic, making systemic pain medication a requirement to provide adequate pain relief for both surgical sites. While pain-control infusion pump systems currently on the market allow for a split catheter insertion, we chose to isolate only the site where the iliac crest bone graft was harvested, as pain is the most common short-term problem associated with this method of obtaining a bone graft. In a study designed in a fashion similar to that of the current study, a difference between treatment and control group could not be determined. Alford and Fadale, in their evaluation of forty-nine patients who had anterior cruciate ligament reconstruction, randomized the patients to three groups¹⁰. Group I received bupivacaine by means of a pain-control infusion pump, Group II received normal saline solution through a pain-control infusion pump, and Group III was not provided a pain-control infusion pump. All patients underwent a femoral nerve block at the end of the procedure. The two groups that received a pain-control infusion pump demonstrated decreased scores on the visual analogue pain scale and decreased narcotic use compared with controls. No difference between the bupivacaine and normal saline-solution groups was detected with respect to the scores on the visual analogue pain scale and narcotic use. This phenomenon might be explained simply by the placebo effect and the effectiveness of a regional anesthetic block that all patients received.

Interestingly, the average pain scores in this study were higher in the treatment group in general and were significantly higher in the treatment group at the twenty-four-hour time-point when the pain scores were evaluated for the recipient site. One can postulate that the increased pain scores at this time-point are a result of relative pain relief at the donor site secondary to the local anesthetic infusion. Hence, the perception of pain at the recipient site may have been magnified. While this seems a plausible explanation, one would have expected a relative and significant increase in pain scores for the recipient site across all time-points in the treatment

group. It is likely that the significant finding at the twenty-four-hour time-point was a chance finding resulting from multiple comparisons. This is not entirely surprising. Studies have indicated that pain perception is a systemic as well as a local phenomenon¹¹⁻¹³. Pain has an impact on the central nervous system that may affect how an individual perceives pain throughout his or her body. Several studies¹¹⁻¹³ have suggested that a person experiencing moderate-to-severe pain in one area would also have a concomitant increase in anxiety that would manifest as increased pain perception across body regions.

Those studies support the findings in our study, which showed that increased pain at the donor site was associated with increased pain at the recipient site irrespective of randomized group. While no study that we know of has specifically examined the ability to discern perception of pain levels between donor and recipient sites in a similar sample, the results of the present study indicate that no additional benefit in terms of pain relief is gained for the patient who has two surgical sites, requires hospital admission, and receives intravenous narcotics.

In conclusion, the results of this small, unstratified study indicate that the continuous infusion of bupivacaine at iliac crest bone-graft donor sites is not an effective pain-control measure in hospitalized patients receiving systemic narcotic medication. ■

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