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A COMPARATIVE STUDY OF TWO DIFFERENT DRUG DELIVERY METHODS OF BUPIVACAINE FOLLOWING SECONDARY ALVEOLAR BONE GRAFTING

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ABSTRACT:

The ilium is commonly utilised for bone harvesting, and several surgical methods have been devised to minimise the related complications. However, the discomfort experienced after surgery at the donor site might be intense, requiring the use of pain relief medication that affects the entire body, which in turn delays the ability to start moving early and hinders the patient's release from the hospital. While local anaesthetic infusion at the harvest site has been recommended as a secure and efficient approach for pain treatment, its effectiveness has not been systematically researched, and not all trials have shown enhanced pain management.

AIM: To determine the best drug administration delivery method for patients undergoing secondary alveolar bone grafting.

MATERIALS AND METHODS: An preliminary, randomised clinical trial was undertaken between October 2022 and October 2023. The study comprised patients who were receiving secondary alveolar bone transplantation. The parameters evaluated included pain measured using the VAS scale, early mobilisation, and the duration of hospital stay. The data entry and statistical analysis in SPSS (version 23.0) were conducted utilising the Microsoft Excel spreadsheet. The study analysed the patients after their surgery. The threshold for statistical significance was established at a p-value of less than 0.05. The paired t-test and Mann Whitney test were employed to evaluate the disparity in means of continuous variables among groups.

RESULTS: The data analysis revealed that patients in group A had a substantially longer duration of pain alleviation (4.2 ± 0.62 hours) compared to group B (6.4 ± 0.43 hours) (Table 2). Group B experienced a notable delay in the time it took for them to start walking (7.2 ± 1.98 hours) as a result of inadequate pain management. Patients in Group A exhibited a notable reduction in pain score during function (4.3 ± 1.03 hours) in comparison to the other groups. However, they reported a shorter period of pain relief compared to Group B. The duration of hospitalisation and the duration of the surgical procedure were the same in both groups.

CONCLUSION: Compared to local infiltration at the surgical site, the administration of bupivacaine through an IV cannula at the surgical site yielded better outcomes in terms of less postoperative pain, a shorter hospital stay, and faster mobilisation. Bupivacaine exhibits a prolonged duration of action and carries a reduced likelihood of cardiovascular and neurotoxic side effects.

Keywords: cleft alveolus, bone grafting, novel method, anesthesia, pain control.

1. INTRODUCTION:

Secondary alveolar bone grafting is a key treatment which is employed to create a connection between the bones in individuals with alveolar clefts, which enables the movement of teeth. This surgery is typically conducted during the canine eruption phase, which occurs between the ages of 7 and 12 years. The positioning of the graft is predominantly influenced by dental maturation, rather than chronological age. Performing a bone graft has several key benefits. Firstly, it offers support for the teeth in the vicinity of the cleft, making it easier for them to emerge. Additionally, it helps to fuse the sections of the maxillary arch and alveolar ridge, leading to improved support for the lips and enhancing the overall appearance of the face.
There are many materials that have been suggested for repairing alveolar clefts, but autologous bone grafts are currently considered the most reliable and effective option. Autologous ilium grafts remain the preferred method for subsequent alveolar bone transplantation. The iliac crest is the most optimal material for alveolar cleft grafting due to its quantity, simplicity of harvest, and the advantage of a two-team approach. Nevertheless, research has uncovered postoperative problems including enduring discomfort at the donor site, extended hospital stay, and delayed ability to walk. The patient's primary worry is postoperative pain, which is reported to be more severe than the pain experienced at the recipient's surgery site in the majority of cases. Administering narcotics systemically effectively alleviates pain, but it is important to note that it can also lead to well-documented adverse effects including nausea, vomiting, excessive drowsiness, and respiratory depression. Studies have demonstrated that various methods can effectively decrease postoperative pain at the donor site. These methods include administering a single dose of bupivacaine, using nerve blocks like femoral nerve block and psoas sheet block, employing epidural anaesthesia, delivering repeated bolus or continuous infusions of the local anaesthetic agent through a catheter, and modifying the surgical technique. No comparative studies have been conducted to compare different bupivacaine drug delivery devices for the management of pain at the donor site. This study aimed to compare the effectiveness of a single indwelling catheter-based analgesia using 0.5% bupivacaine with repeated rescue bolus infusions, to the control of a single-dose 0.5% bupivacaine infiltration, for managing postoperative pain after anterior iliac grafting in paediatric cleft alveolus repair.

2. METHODS AND MATERIALS

Study layout: The study was conducted as a prospective, double-blind, randomised clinical trial. It began after receiving ethical approval from an institution (IHEC/SDC/OMFS-2101/23/166) by the institutional review board. Patients were enrolled after getting this approval. The study sample consisted of children between the ages of 8 and 12 who needed a bone grafting procedure from the front part of the hip bone (anterior iliac crest) on one side. The study was conducted between May and December 2022. Explicit consent in writing was obtained from both the parents and accompanying guardians of all the children participating in the study.

Table 1: The demographic attributes of the research population

Study variable	Group A	Group B
Sample size, n	20	20
Age, mean ± SD, years	10.4 ± 1.3	9.8 ± 1.7

Sex: male, female	8,12	9,11

The study included patients between the ages of 8 and 12 who had unilateral alveolar clefts classified as American Society of Anaesthesiology grade I (ASA I) and had not previously had iliac bone harvest. Exclusion criteria for this study included patients who were not classified as ASA I, patients who declined to participate, patients with bilateral alveolar cleft deformity, patients with systemic diseases or associated craniofacial syndromes, patients taking medications that could affect the study's outcomes, and patients with known allergies to local anaesthesia. Crucially, there were no instances of individuals being removed from the experiment due to any negative consequences or side effects throughout its entire duration. The demographic attributes of the research population are presented in Table 1.

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Procedure and data collection

The surgical procedures were performed under general anaesthesia. Fentanyl, at a dosage of 2 mg per kilogramme of body weight, was the sole analgesic supplied during the induction phase. During the surgery, a thin tube called an 18-gauge IV cannula is inserted beneath the periosteum layer after removing bone from the iliac area. The correct placement of the cannula is confirmed by visual examination. The cannula was fastened in place using an adhesive bandage and micropore tape. In group A patients, a standardised dosage of 0.2–0.3 ml/kg body weight, with a maximum permitted dose of 2 mg/kg body weight, of 0.5% bupivacaine was delivered through the indwelling cannula (18G). Patients in Group B, who served as controls, were administered a single-dose depot injection of 2 ml of 0.5% bupivacaine subcutaneously after the bone harvest procedure was finished.

Postoperative pain management

Patients in Group A were administered 0.5% bupivacaine through an indwelling cannula for on-demand rescue doses of analgesia, along with oral paracetamol. Both groups A and B were administered placebos in addition to the oral ibuprofen. The dosage for the rescue bolus was determined to be 0.2-0.3 mL per kilogramme of body weight.

Evaluation of Results

After the surgical procedure, all patients were moved to the recovery room, where their levels of conscious pain were measured and documented. The main evaluation of the outcome was a subjective assessment of the severity of pain both at rest and during activity, use the Wong-Baker FACES rating scale. Pain levels were documented at 6-hour intervals for a duration of 48 hours after the surgical procedure. The functional results were assessed by observing pain levels during walking and pain levels during elevating the leg. The time until the greatest pain score, the time until the initial ambulation, the duration of analgesia, and the length of hospital stay were all documented. The patients were admitted to the hospital until they felt secure enough to go back to their homes. The duration of hospital visits was also recorded.

Statistical analysis

The statistical examination incorporated the use of the paired T-test and Mann-Whitney test. A p-value of 0.05 was deemed to have statistical significance. The statistical data was analysed using SPSS for Windows version 23.0 (IBM Corp., Armonk, NY, USA).

3. RESULTS:

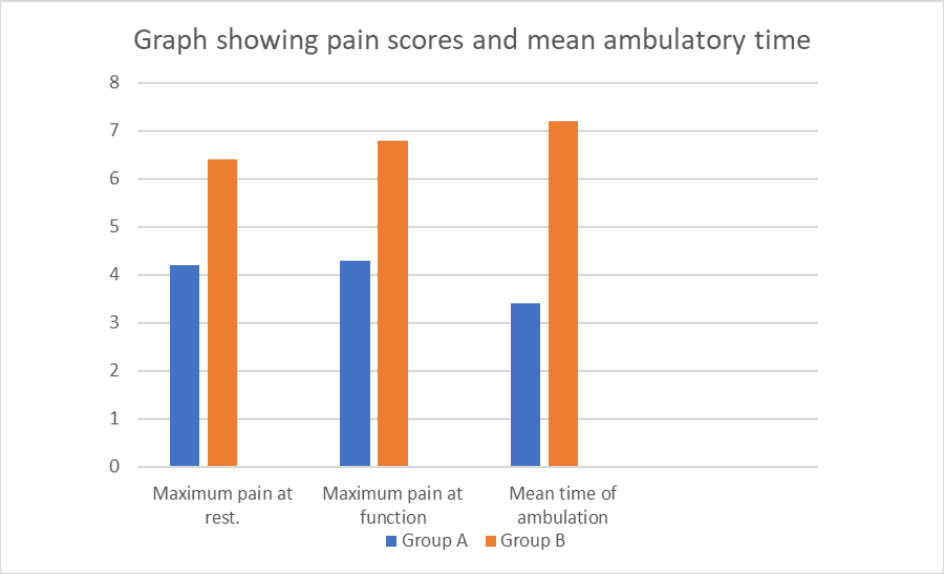
The duration of pain relief was substantially longer in patients from group A (4.2 ± 0.62 hours) compared to those from group B (6.4 ± 0.43 hours) (Table 2). Group B experienced a notable delay in their ambulation time (7.2 ± 1.98 hours) as a result of inadequate pain management. Patients in Group A exhibited a notable reduction in pain score during function (4.3 ± 1.03 hours) in comparison to the other groups. However, Group A had a shorter duration of pain alleviation compared to Group B. The duration of hospitalisation and surgical procedure were equivalent in both groups. (Table 2)

VARIABLES	GROUP A	GROUP B	P- VALUE
Maximum pain at rest.	**4.2 ± 0.62**	**6.4 ± 0.43**	**0.005***
Maximum pain at function	**4.3 ± 1.03**	**6.8 ± 1.9**	**0.003***
Mean time of ambulation	**3.4 ± 1.20**	**7.2 ± 1.98**	**0.004***

Table 2: The duration of pain relief

No complications related to the catheter, such as kinking, infection, or extrusion, were seen. The removal of all catheters occurred 48 hours after the surgical procedure, and patients were discharged on the third day following the operation. Both groups experienced a steady decline in pain scores over a period of 48 hours. However, group A had the most significant drop, leading to an early return of function.

Graph 1: Pain scores and Mean Ambulatory time.



4. DISCUSSION:

Local anaesthetic drugs are recognised for their ability to temporarily induce anaesthesia and alleviate pain in a specific location, as evidenced by several research investigations. There are multiple well-documented techniques for administering local anaesthetic at the surgical site, such as nerve blocks, depot injections, epidural anaesthesia, and infiltration through the indwelling catheter. Liu et al. performed a comprehensive systematic review of randomised controlled trials, incorporating both quantitative and qualitative analyses. Continuous wound catheters have been found to offer many advantages, such as enhanced pain relief, decreased reliance on opioids and their associated adverse effects, heightened patient contentment, and shortened hospitalisation duration. The aforementioned review also documented a 1% occurrence of technique failures in the administration of local anaesthesia, as well as a 0% occurrence of local anaesthetic toxicity resulting from the use of continuous wound catheters.

The purpose of the present study is to compare and identify the most effective way of drug administration for patients who are undergoing secondary alveolar bone grafting in order to alleviate pain after the extraction of bone from the iliac crest. Our study findings indicate that catheter-based anaesthesia (Group A) exceeded Group B in terms of providing effective pain relief, facilitating early ambulation, and reducing hospitalisation duration. The usual pain treatment procedure used in most centres involves providing systemic medicines after surgery. This study aims to mitigate the long-lasting negative effects associated with analgesics by utilising localised administration of anaesthetic agents for pain management. Administering local anaesthetics at the donor site enhances pain tolerance, resulting in less discomfort at the surgery site. Additionally, it minimises the requirement for higher doses of systemic medication, thereby mitigating the associated toxic side effects.

Previous research has been carried out, demonstrating that the inclusion of bupivacaine-soaked absorbable gauze at the donor site resulted in less discomfort, decreased reliance on post-operative systemic analgesics, and facilitated early ambulation. Wilson Kennedy and Hiranaka discovered that administering drugs locally through an epidural catheter during iliac graft harvesting was a highly successful approach for alleviating pain. Ensuring patient affordability will be crucial in our institutional context. Our technique is cost-effective since catheters are readily accessible in an operating theatre setup and have a low cost.

Catheter-based anaesthesia has several demonstrated advantages, such as a reduced infection rate when removed within 48 hours, a straightforward technique that may be done at the bedside, the capacity to administer a rescue bolus as needed, and improved patient well-being. The study's strengths lie in its prospective nature, double-blind design, and the use of randomization to mitigate bias. The cohort examined was homogeneous in terms of age, with individuals aged between 9 and 12 years. Additionally, all surgical interventions were carried out by a sole surgeon, adhering to a standardised surgical protocol. The study is limited by a small sample size and the administration of rescue bolus anaesthetics upon patients' request, which may result in deviations in the pain score results.

5. CONCLUSION:

Based on our findings, we conclude that the indwelling catheter-based analgesic strategy is the most efficient of the three methods presented in this study. This technique enables the patient to receive rescue boluses of 0.5% bupivacaine as required. It offers substantial pain relief and

enables a prompt return to normal activities, enhancing overall patient satisfaction after surgery.

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