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A PROSPECTIVE STUDY ON THE EFFECT OF COMBINING INTRAOPERATIVE INFILTRATION OF 0.25% BUPIVACAINE HYDROCHLORIDE WITH INTRAMUSCULAR KETOROLAC FOR IMMEDIATE POSTOPERATIVE ANALGESIA IN ORTHOGNATHIC SURGERY

Anesthesiology

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ABSTRACT

Aim: Comparing the efficacy of administering a combination of local infiltration with bupivacaine HCl 0.25% and intramuscular.(IM) ketorolac to IM ketorolac alone during the postoperative period of orthognathic surgery.

Materials and methods: This study was conducted at the Department of Oral and Maxillofacial Surgery, Saveetha Dental College and Hospital, Saveetha University, Chennai. Seventy patients who underwent bi-jaw orthognathic surgery under general anaesthesia were included in this study. The surgical procedures were performed by surgeons with similar levels of experience, identical operating conditions and using standardized techniques. Any patient who had to undergo additional procedures were excluded from the study. Patients allotted to the Study Group received 0.25% Bupivacaine HCl with 1: 200000 concentration of adrenaline solution as infiltration at the surgical site and a dose of IM ketorolac 30 mg. Patients who had been allotted to the control group were given IM ketorolac 30 mg alone.

Results: Comparison of study and control group with respect to the number of minutes passed before the first rescue analgesic administration, the total number of analgesics administered at the end of 72 hours and with the overall VAS scale was done with an independent t-test. The p-values were <0.0001, <0.0030, and <0.003 which showed highly significant statistical values.

Conclusion: Our study showed that intraoperative wound infiltration with 0.25% bupivacaine was effective in reducing the pain and analgesic consumption by the patient in the postoperative period.

KEYWORDS

Bupivacaine, ketorolac, bupivacaine and ketorolac, orthognathic pain management

INTRODUCTION

Orthognathic surgery is a routine procedure performed by oral and maxillofacial surgeons and has been indexed with high postoperative pain scores (Niederhagen, Braumann, Dierke-Dzierzon, & Albrecht, 1997). This has made postoperative pain management a fascinating subject in the field of medicine. In particular, the negative effects of inadequate analgesia have aided in bringing this particular subject to the forefront (Karanikolas & Swarm, 2000).

Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (Merskey, 1979). Optimization of analgesia is of prime importance in postoperative patients. It helps in decreasing the postoperative mortality and morbidity. Concurrently, good analgesia increases patient perception and acceptance of the surgical procedure (Ballantyne, 2004). This can be achieved primarily by two methods-local infiltrations and by parenteral administration. The former has the advantages of having reduced pain on resting and motion that allows better patient ambulation aiding recovery, but each of the techniques used for local delivery has its own disadvantages.

At this time when local anaesthetic has become an integral part of the multimodal drug regime, we are comparing the efficacy of administering a combination of local infiltration with bupivacaine HCl 0.25% and intramuscular (IM) ketorolac to IM ketorolac alone during the postoperative period of orthognathic surgery.

MATERIALS AND METHODS

This study was conducted at the Department of Oral and Maxillofacial Surgery, Saveetha Dental College and Hospital, Saveetha University, Chennai. The study design was formulated using STROBE guidelines and approval from the institutional committee was obtained. This was a randomized controlled clinical study. Duration of the study was decided as 18 months. Seventy patients who underwent bi-jaw orthognathic surgery under general anaesthesia during this period were included in this study. Patient randomization followed the lottery method and was allotted into the study group and the control group. Patients and their guardians were informed about the study and procedure, and informed consent was obtained from those who were willing for the study.

Inclusion criteria

1. ASA I and ASA II patients
2. Age of the participants: 15 to 35 years old
3. Bi-jaw orthognathic surgery
4. Patients who had 72 hours or more of hospital stay following the surgery. (Post-operative period of > 72 Hours)

Exclusion criteria were as follows:

1. Patients with a history of asthma, cardiovascular diseases, thyrotoxicosis, liver diseases, etc.
2. Extra-oral surgical site (Extra-oral approach for osteotomy or bone grafting)
3. Less than 72 hours of hospital stay.
4. Other procedures combined with Orthognathic surgery like Rhinoplasty, Distraction Osteogenesis, Closure of Cleft Lip or Palate, Closure of Oroantral Fistula
5. Allergic reaction to Bupivacaine or Ketorolac.

After completing all the preoperative treatment planning, the patients were taken up for the surgery. On the day before the surgery, the patients who were allotted to the study group were given counselling and the protocols of the study were explained to them. Test doses for all the drugs were done a day before the surgery.

After following the normal protocol of pre-anaesthetic medications,

antibiotics and steroids, the patient was taken up for the surgery. The surgical procedures were performed by surgeons with similar levels of experience, identical operating conditions and using standardized techniques. Any patient who had to undergo additional procedures like anterior maxillary osteotomy were excluded from the study.

Immediately after the wound closure, the patients allotted to the Study Group received 0.25% Bupivacaine HCl with 1: 200000 concentration of adrenaline solution as infiltration at the surgical site and a dose of IM ketorolac 30 mg. The 0.25% bupivacaine HCl solution was freshly prepared before the surgery. It's prepared by diluting 5 ml of 0.5% Bupivacaine HCL (ANAWIN or SENSORCAINE) by adding 4 ml of distilled water and 1 ml of 1: 2,00,000 concentration of adrenaline. 1 ml to 2 ml of solution was infiltrated into the osteotomy sites at each reference points to make 10 ml of solution in each jaw. The reference points have been described in Table 1. The patients who had been allotted to the control group were given IM ketorolac 30 mg alone.

Post general anaesthetic reversal, the patients were shifted to the recovery area and was administered with antibiotics and dexamethasone. The time of administration of the medications immediately after the closure was noted and the duration between that, and the time of administration of the first rescue analgesic was recorded. A visual analogue scale was constructed to assess the pain – a low score of zero indicating no pain and a high score of five indicating severe pain. This was provided to the patient, past 72-hours, for the overall assessment of pain. The combined number of rescue analgesics were also noted, although it did not play any pivotal role in the study.

Statistical analysis

For analysis of the data, a non-parametric test, the Mann-Whitney test was applied. Since the variable age and weight followed a normal distribution, an independent samples t-test was applied. To compare proportions, the Chi-square test was used. All the data analysis was performed statistical package for social sciences (SPSS), Version 20.0 (IBM, Armonk, New York, USA).

RESULTS

Out of the 70 patients included in the study, 41 were females and 29 were males. The mean age for the study group was 22.5 and for the control group was 23.22. The mean weight of the patients in the study group was 54.54, and that in the control group was 54.37. All the patients underwent both LeFort I osteotomy and bilateral sagittal split osteotomy. The VAS scale values of the two groups were compared, and the p-values assessed.

Comparison of study and control group with respect to the number of minutes passed before the first rescue analgesic administration, the total number of analgesics administered at the end of 72 hours and with the overall VAS scale was done with an independent t-test. The respective p-values were <0.0001 (Table 2), <0.003 (Table 3), and <0.003 (Table 4) which demonstrates high statistical significance.

DISCUSSION

Postoperative pain is considered as a form of acute pain due to surgical trauma, characterized by incisional damage to skin or mucosa and various other tissues, application of thermal and chemical stimuli to the wound, and often prolonged traction and manipulation of soft tissues with an inflammatory reaction and initiation of an afferent neuronal barrage (Chaturvedi, Chaturvedi, & others, 2007). The inflammatory mediators released as a result of trauma activate the primary afferent nerves which in turn can evoke changes at the level of the spinal cord, a process referred to as "peripheral sensitization." If acute pain is not properly managed, prolonged activation of pain pathways can lead to further neuro-physiological changes, collectively called "central sensitization", which may prolong recovery and convert acute pain to chronic condition (Mehlisch, 2002).

Currently, two classes of drugs are used to treat post-operative pain – NSAIDs and opioids, both of which possesses its own merits and demerits often related to the dose and mode of administration. The search of appropriate newer combination for the satisfactory pain relief in the post-operative period has led to the concept of balanced analgesics. This refers to the use of multiple analgesic agents to selectively affect several of the physiologic processes involved in nociception, transduction, transmission, and modulation. Such combination therapy may represent the most effective regimes available for the control of the postoperative pain (Clarkson & Hondeghem, 1985; d'Amours & Ferrante, 1996).

Approaches to the measurement of pain include verbal and numeric rating scales, VAS, behavioural observation scales and psychological responses of these, the VAS is the most frequently used self-rating scale. The advantage of VAS includes ease of scoring, its minimum intrusiveness, it's greater sensitivity to detect intervention based changes in pain and its conceptual simplicity (Melzack & Katz, 2006). Bupivacaine is a long-acting local anaesthetic belonging to the amide group. Toxicity is related to the plasma level of the unbound drug and is most likely to be seen after intravascular injection. Due to the high protein binding capacity, cardiac resuscitation at times of cardiac toxicity is difficult due to strong binding with sodium channel is myocardial muscle (Melzack & Katz, 2006) (mostly after intravascular injection). Ketorolac is a member of Pyrrolopyrrole group of NSAIDs. It possesses analgesic, anti-inflammatory, and antipyretic activity. A recent retrospective trial of more than 20,000 patients showed that parenteral Ketorolac causes a higher incidence of both gastrointestinal and surgical sites bleeding (Shankariah, Mishra, & Kamath, 2012) .

Among the techniques to reduce postoperative pain, wound infiltration with long-acting anaesthetics has a substantial role. Wound infiltration with long-acting local anaesthetics like Bupivacaine HCl is widely used as a method of postoperative analgesia in various fields of surgery (Akhtar, Saleem, & Zaheer, 2009) . The study was done to compare the efficacy of preoperative infiltration of 0.25% Bupivacaine with intramuscular ketorolac and ketorolac alone for effective postoperative pain relief in orthognathic surgeries.

The overall VAS scale and the total dosage of the IM analgesic had decreased significantly. Hence, it is evident intraoperative infiltration with Bupivacaine, not only decreases the postoperative pain but also helps to reduce the dosage of IM Ketorolac. This can be explained by the fact that maximal pain experience occurs during the first 9-12 hours of the post-operative period. Bupivacaine due to its prolonged action and its ability to slow return of the normal sensation provides satisfactory analgesia during this time period and then reduces the analgesic consumption. There are many trials of hernia repair in the literature and all have proved excellent results in the infiltration of Bupivacaine alone (Akhtar et al., 2009) .

CONCLUSION

Effective pain relief is an essential requirement for all surgical procedures. Multimodal analgesia protocol can be employed to hasten the recovery and improve the outcome. Our study showed that intraoperative wound infiltration with 0.25% bupivacaine was effective in reducing the pain and analgesic consumption by the patient in the postoperative period. The comparative results clearly demonstrate that wound infiltration with bupivacaine (<0.001) is significantly effective than with intramuscular ketorolac alone in postoperative analgesia in orthognathic surgery cases.

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Table 1 Reference points for the administration of bupivacaine solution

Si No.	Procedure	Reference Points	Volume Of Solution (ml)
1.	LeFort I osteotomy	Infiltration i.r.t upper Right First Molar	2
		Infiltration i.r.t upper Left First Molar	2
		Infiltration i.r.t upper right first or second premolar	2
		Infiltration i.r.t upper left first or second premolar	2
		Infiltration i.r.t upper Central Incisors	1
2.	Anterior maxillary osteotomy	Infiltration i.r.t upper right first or second premolar	2
		Infiltration i.r.t upper left first or second premolar	2
		Infiltration i.r.t upper Central Incisors	1

3.	Lower segmental osteotomy	Infiltration i.r.t lower right first or second premolar	2
		Infiltration i.r.t lower left first or the second premolar	2
		Infiltration i.r.t lower Central Incisors	1
4.	Bilateral sagittal split osteotomy	Infiltration i.r.t to right buccal osteotomy cut	2
		Infiltration i.r.t Left Buccal Osteotomy cut	2
		Infiltration i.r.t to right lingual osteotomy cut	2
		Infiltration i.r.t Right Retromolar region	1
		Infiltration i.r.t left Retromolar region	1
5.	Genioplasty	Infiltration i.r.t Right lower Canine	2
		Infiltration i.r.t Left lower Canine	2
(i.r.t – in relation to)		Infiltration i.r.t lower Central Incisors	1

Table 2 Comparison of study and control group with respect to the number of minutes passed before the first rescue analgesia

Groups	Mean	SD	t value	P value
Study	460.00	52.34	13.96	<0.001**
Control	280.28	55.05		

Independent t-test; (p< 0.05 - Significant*, p < 0.001 – Highly significant**)

Table 3 Comparison of study and control group with respect to the total number of rescue analgesics administered-72hrs

Groups	Mean	SD	t value	P value
Study	4.14	1.26	3.13	0.003*
Control	5.02	1.09		

Independent t test; (p< 0.05 - Significant*, p < 0.001 – Highly significant**)

Table 4 Comparison of study and control group with respect to Overall VAS scale

Groups	Mean	SD	t value	P value
Study	9.28	6.65	3.12	0.003*
Control	14.85	8.17		

Independent t test; (p< 0.05 - Significant*, p < 0.001 - Highly significant**)

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